

### ANNUAL REPORT



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## Letter from the Chairman

It's not easy to write about the events of last year, as such a lot has happened between the end of the year and June 2012.

But firstly I would like to congratulate the new government and in particular the President of the Community of Madrid, who has been re-elected to her post.

I also want to express my thanks to the General Council of the Official Colleges of Pharmacists for the Panorama prize they awarded to ROVI, the Corporation of the Official College of Pharmacists of Granada for the Gold Medal, and Madrid Healthcare for the Medal they kindly awarded me this year.

But these awards, welcome though they are, should not distract us from our main responsibilities and I would like to emphasise that 2011 was another excellent year for ROVI.

As you will remember, last year I and many others said that it would take some time for Spain to return to growth after years of crisis: no-one is forecasting an early end to this recession. But as I explained last year, ROVI has made the decision to adapt to these difficult circumstances.

I would also like to confirm some of the initiatives that ROVI is implementing to overcome this situation:

We have spent many years building our international markets. We are present in 46 countries, and directly and indirectly these markets represent almost 10% of our sales volume.

#### Support for local manufacturing

Spain has an enormous deficit in industry. There are many reasons for this, and one of the ways of making sure that the deficit does not increase is to keep existing plants open and support local manufacturing.

We all have a responsibility and a part to play, and at ROVI we are expanding our production units. This has also resulted in an increase in employment. ROVI increased its workforce by 4% in the year, to 834 people.

In our sector, the contraction of the pharmaceutical market has resulted in redundancies and dismissals and the closure of plants.

The Government has cut the price of pharmaceuticals while forgetting that imports of medicine must be paid for somehow, and that the pharmaceutical plants in Spain create employment, pay for Social Security, and ensure national supplies.

#### Innovation

Innovation does not mean just building another motorway, which can be constructed at any time. Innovation is a long term commitment: there must be a commitment to innovation and an understanding of all the uncertainties that it implies. There must be a pact from the State – a commitment from the government to the companies and citizens of Spain.

It is a concern that the Government will cut investment in innovation. But at ROVI we continue to innovate and we expect to be recording positive EBITDA and profits from this innovation in 2014.

There is no room for improvisation in the pharmaceutical industry. Innovation is our guiding principle, and I would like to thank our shareholders, employees and management for their continued commitment to innovation.

#### **Exports**

Everyone in Spain is calling for more exports. While all countries are trying to increase their exports, others, especially developing countries, are also focused on importing.

At ROVI we have spent many years building our international markets. We are present in 46 countries, and directly and indirectly these markets represent 32% of our sales volume.

We will remain committed in particular to the Asian market. We expect to be able to disclose promising news about the strategic expansion of the Company, based on the molecule we have developed at ROVI - Bemiparin.

#### **National Market**

The price of pharmaceuticals in Spain has fallen by 41.5% since 2003. In 2011 alone, prices dropped by 10%. Prices in Spain are now below levels of countries such as Cyprus, Malta, Estonia, Latvia and Portugal.

This is a very complicated situation. Spanish healthcare is not responsible for the deficit. Many other countries invest a lot more of GDP in their healthcare systems. But it is one of the best medical systems in the world. To study medicine at university, an entrance score of 9 is required, and the structure of the courses has led to our number three ranking worldwide. However while the government debates tax cuts, it is forgetting just how much the sector pays in taxes and how much it contributes to some of the highest levels of social security in all Europe.

The Government needs to form a pact with the Healthcare sector. CEIM and the Madrid Chamber of Commerce have called for this and have requested the support of the CEOE, the Spanish employers association, which has produced an excellent report on the sector.

Pharmacists and the business community feel they are not being recognised in the values of Spanish society.

Healthcare is an essential part of our society. It is medicines that cure diseases, lengthen life, enhance the quality of life and act against chronic diseases.



But all of this depends on innovation. And innovation must be paid for.

I would like to conclude by extending my warmest thanks for the efforts that the people who work at ROVI have dedicated to the Company this year. Their commitment and enthusiasm is central to our mission and are the real drivers of our Company. They are the guarantee that 2012 will be another year of growth and success for us.

I would also like to thank our shareholders for their loyalty to ROVI and their continuing support for the Board of Directors.



Juan López-Belmonte López Chairman

## ROVI in 2011 Main numbers

## 2011 was a significant and positive year for ROVI...

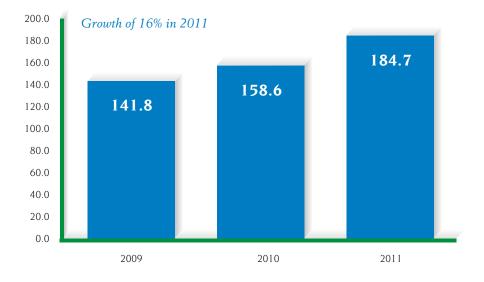
- Results in line with strategic targets.
- Significant increase in sales of prescription-based pharmaceutical products (15%), driven by the strength of Bemiparin, our flagship product, with sales up 14%.
- Market share of Bemiparin at **22%** in Spain.
- Launch of Bemiparin in **4** new countries.
- **2** new product launches in 2011, although they are considered as one product in terms of the marketing rights granted to ROVI by MSD:
  - Absorcol, whose active principle is ezetimibe, and
  - Vytorin, which combines two active principles, ezetimibe and simvastatin.
- Toll manufacturing sales increased by **28%**.
- First financial full year after the implementation of the Strategic Pharmaceutical Manufacturing and Marketing Agreement with Merck Sharp & Dohme (MSD) in Spain in 2010. Revenues from this agreement amounted to **32.2** million euros in 2011.
- Signing of a contract with Farmalíder for the manufacturing of oral forms.

- Alentia Biotech, a joint venture of Ferrer and ROVI, signed an agreement with Novartis Vaccines & Diagnostics for the production of vaccines against seasonal and pandemic flu.
- Positive results of the Risperidone-ISM Phase I study.
- Dividend proposal of 35% of consolidated net profit for 2011 at the General Meeting of Shareholders.
   Payment of a gross dividend of 0.1269 euros per share on 2011 earnings.

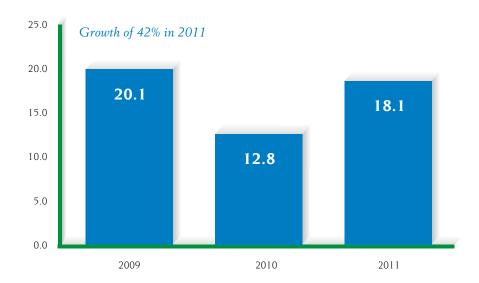


## ...which delivered

• Operating revenues of **184.7** million euros.



• Recurrent net profit of **18.1** million euros.



Letter from the Chairman • ROVI in 2011 • Activities report • Management report Company information • Corporate social responsibility • Corporate governance • Financial report

## ROVI in 2011 2011, the year in headlines

### January

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 Mart
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in Farm

**hypcholestorolemia.** Globedia 18 January 2011

ROVI to sell Vytorin®

and Absorcol<sup>®</sup> to treat

OCAP technology does not achieve gastrointestinal absorption of Bemiparin administered orally.

Im Farmacias 18 January 2011

Laboratorios Rovi obtains contract with Farmalíder.

Ahorro.com 31 January 2011

12.

### February

Francisco de Paula Lombardo, new director of Rovi.

La Opinión de Granada 23 February 2011

### Rovi earnings up 22% in the last year.

Negocio & Estilo de Vida 25 February 2011

Rovi monetizes agreement with MSD and revenues increase 12% in 2010.

El Global 25 February 2011



#### Rovi logró ganar un 22% más el ejercicio pasado

Laboratorios La facturación de la factocidatico pursenta o 360,3 milionescile ecuros os 501 milionescile ecuros

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### April

#### . GRANADA

#### La planta de vacunas se quedará en Granada

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Aller To delet manageria per manageria per manageria manageria del contente contente del contente da cont Rovi adjusts its sights to tackle cancer.

El Economista 6 April 2011

Experts advise the use of 'Thymanax' (Rovi) as an alternative for fighting depression.

Diario Salud 8 April 2011

### The vaccines plant will stay in Granada.

Ideal 22 April 2011

### May

Rovi revenues increase by 40% in the first quarter.

Infofarma 12 May 2011

Rovi cooperates with SECOT in the Orthopedic Surgery and Traumatology Course for final year residents.

Terra 13 May 2011

Rovi forecasts an increase in Ebitda of 25% to 30% to 2014.

Negocio & Estilo de Vida 18 May 2011 Ivabradine leads to improvements in patients with chronic cardiac insufficiency.

Acta Sanitaria 26 May 2011



### June

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17 June 2011

### July

### Rovi has potential upside to over 6 euros.

Capital Madrid 1 July 2011

Laboratorios Farmacéuticos Rovi to distribute a dividend of 0.17 euros on Wednesday.

Finanzas 5 July 2011

Rovi announces positive results for the monthly injectable formulation of Risperidone-ISM.

Periodista digital 11 July 2011

Rovi increases revenues by 32% in the first quarter, to 95.9 million.

Europapress 28 July 2011



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August

### The PSOE announces that the PTS vaccine plant will be a reality in September.

Ideal 13 August 2011

### September

Corlentor (Rovi) improves the quality of life of patients with cardiac insufficiency.

Informativos Telecinco 2 September 2011

#### Our data demonstrate the effectiveness of Thymanax on anxiety during depression.

Acta Sanitaria 5 September 2011 Rovi and Ferrer join forces against influenza, with a pioneering factory.

Expansión 22 September 2011

#### **Rovi creates Alentia Biotech** to establish its vaccines plant.

Granada Hoy 24 September 2011





### October



Rovi to look for a partner in oncology following good results from Bemiparin.

El Periódico Mediterráneo 19 October 2011



### November

Rovi earns 36% less to September, with lower extraordinary income.

Cinco Días 8 November 2011

#### Psychiatrists and doctors from AP, with the support of Rovi, agree on recommendations for patients with depression.

Acta Sanitaria 11 November 2011

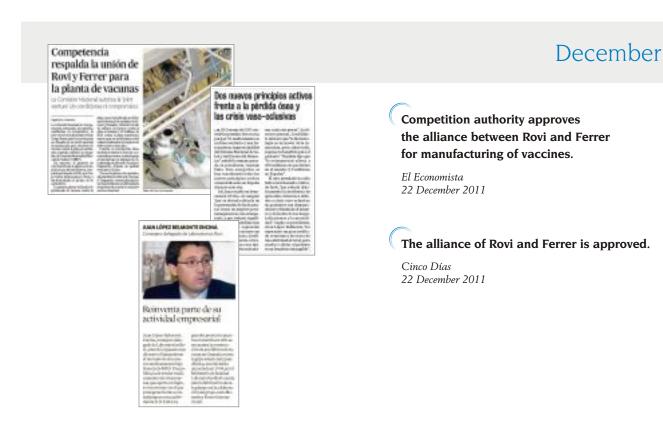
Ferrer informs Competition Authority of acquisition of 50% of Alentia Biotech.

Alimarket 16 November 2011 Laboratorios Rovi: growth without doubts.

Bolsamanía 22 November 2011



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## Activities report R&D

## ROVI, committed to research

During the 20th and 21st centuries, the so-called "knowledge society" has displaced the former model of industrial society. While in the past the wealth of countries was generated by large farms and huge factories, nowadays national wealth stems, among others, from the research and innovation carried out at small or large technological centres that each contribute with their achievements to the increased productivity of their respective economies.

It is clear that the countries with the greatest growth are those where companies have been successful and have been able to generate added-value products that are then exported to the rest of the world.

The success of the companies is tied to the achievements of his investigation and innovation.

This has led us to the conclusion that the companies that operate successfully in modern society are those that are rich in knowledge. Today, the success of companies is based above all on the achievements of their industrial research and innovation.

ROVI is a company that is committed to research. Its success can be clearly seen in the extraction of the first

second generation low molecular weight heparin, Bemiparin (HIBOR®), currently present in 46 countries.

In view of ROVI's research commitment, it is essential to protect any inventions that might arise in the course of this research and this protection is mainly achieved through the patent system.

The generation of patents titles and industrial know-how is a clear reflection of the innovative work carried out by ROVI. The laboratory currently has a solid patent portfolio, comprising more than 100 granted patents and over 30 pending applications.

### Our innovative approach

ROVI has always stood out for our highly defined approach to innovation and our commitment to investment in research, as we believe that the future of the company depends on carrying out these activities. Research and innovation are essential and strategic in order to compete in the modern market, and are crucial in order to differentiate ourselves from other companies in the sector.

With this in mind, ROVI has two R&D&I centres following the creation of a new research centre covering more than 1,300 m<sup>2</sup> located in the Parque Tecnológico de las Ciencias de la Salud de Granada, in the most important Spanish Biopharmaceutical cluster.

Since 2006, ROVI has been present in the creation of



major national research consortia. In 2006, the research activities of the NANOFARMA Consortium began as part of a large biomedicine project focused on research into controlled drug release within the framework of the CENIT programme (the Spanish National Strategic Consortia for Technical Research), an initiative of the current government included within the "Ingenio 2010" Programme.

ROVI has been also present as an active participant in other consortia and national plans, including the MELIUS CENIT Consortium of pharmaceutical and biotechnological companies, in 2009 the CEYEC CENIT Consortium and, since 2011 as leader of the SNCintegra (FEDER Innterconecta) consortium and the National PROFARMA Plan for the encouragement of R&D&I in the pharmaceutical industry, within which ROVI has obtained, for the fourth year in a row, the recognition of "excellent," based on our ongoing research efforts in R&D&I, the quality of the projects under way and the recent internationalization of our products.



Our research

#### 1. Drug delivery technologies

One of the most important stages in the development of a drug is the study of how it should be administered. The right administration has a direct effect on the drug's efficacy, as it influences factors such as its pharmacokinetics, pharmacodynamics, safety, immunogenicity, and bio-recognition of the drug, among others. On the other hand, investigation in this field also enables the minimization of such factors as degradation of the active substance, allows the prevention of side effects and increases the bio-availability of the drug in the body. ROVI has developed a leading-edge research line in the field of prolonged release or depot systems, by using the ISM technology. This technology is based in the formation of "in situ" forming implants for long-term release of drugs.

#### 1.1. Extended release systems: ISM<sup>™</sup> (In Situ Microparticles system)

In situ forming systems (ISM $^{TM}$ ) have emerged as a very attractive possibility for the extended release of bioactive macromolecules.

Over the last few years, the development of ISM<sup>™</sup> has been very fast and has made it possible for depot formulations to become a scientific fact. A depot injection is generally a subcutaneous or intramuscular injection of a pharmacologically active agent that releases the active substance in a constant flow over a long period of time.

ISM<sup>™</sup> technology is based on a solid and stable polymeric matrix system of drug, excipients and solvent. The product is reconstituted before administration to an injectable fluid that precipitates in situ (inside the body) after the injection, resulting in the formation of solid/semisolid implants, by solvent diffusion to body fluids.



ISM<sup>™</sup> technology overcomes most of the current difficulties associated with the production and use of oral and parenteral extended release formulation combining the advantages of existing technologies such as preformed microparticles and implants. It allows the extended delivery of compounds administered by parenteral via with the following key advantages: less variability, enhanced stability, rapid reconstitution and easier injectability, making it easier for the patient to follow the prescribed treatment.



The main advantages are: less variability, enhanced stability, rapid reconstitution and easier injectability, making it easier for the patient to follow the prescribed treatment.

ISM<sup>™</sup> systems have the following advantages over technologies existing in the market: (I) ease administration as it is less painful, (II) zero-order kinetics, (III) reduction of the burst effect in drug release and greater reproducibility in the release profiles, (IV) highly effective encapsulation, (V) high performing process and, finally, (VI) improvement in the stability of the active substance.

The establishment of this novel field of research in ROVI arose from the interest showed by the company in the development of formulations based on ISM<sup>™</sup> technology with the aim of allowing periodic administration of formulations which are administered daily in chronic and prolonged treatments, improving the patient's quality of life. This novel approach allows ROVI to enter and compete in new therapeutic areas. Extended release formulations based on ISM<sup>™</sup> technology are currently being developed for psychiatric and oncologic drugs due to their industrial potential and commercial and sanitary interest.

In September 2010, the experimental stage began for the first Phase I trial of Risperidone-ISM<sup>™</sup> on healthy volunteers, the first candidate for this drug delivery system. This



first trial aimed mainly to evaluate the pharmacokinetics and the tolerability of a single intramuscular administration of risperidone in an ISM<sup>™</sup> formulation. This trial has served not only to confirm the pharmacokinetic profile of this innovative depot formulation for the monthly administration of a recognised anti-psychotic, but it has served as proof of concept for validating ISM technology as a base platform for other developments. In this regard, other new formulations with ISM<sup>™</sup>, for the monthly administration of another widely used anti-psychotics (paliperidone and olanzapine), and for the quarterly administration of a recognised aromatase inhibitor (letrozole) that is currently used extensively in the treatment of hormone-dependent breast cancer, are already in an advanced pre-clinical phase.

#### 1.2. Clinical research: ISM<sup>™</sup> (In Situ Microparticles system)

ROVI has already initiated the research program with this technological platform for some compounds and currently there are several projects on different development phases: • ISM Platform for antipsychotics: in September 2010, the clinical testing stage began for the first Phase I trial of Risperidone-ISM<sup>®</sup> on healthy volunteers and finished by the end of the first guarter of 2011. This first trial aimed mainly to evaluate the pharmacokinetics and the tolerability of a single intramuscular administration of risperidone in an ISM formulation<sup>1</sup>. In July 2011, ROVI disclosed the positive results obtained from this phase I clinical trial<sup>2</sup>. The analysis of the data showed that ISM technology enables the sustained delivery of risperidone from the first day, which will allow for once-monthly administration without the need for supplementary oral risperidone in the first weeks. These characteristics will facilitate the adherence with treatment of schizophrenic patients, and represent an improvement on the risperidone formulations that are currently available. The full results were presented at the 3rd European Conference on Schizophrenia Research held in Berlin in September 2011<sup>3</sup>.

(1) Phase I study # NCT01320410. http://www.clinicaltrials.gov/ct2/show/NCT01320410?term=rovi&rank=3

<sup>(2)</sup> Laboratorios Farmacéuticos Rovi, S.A. ROVI announces positive results from the Phase I trial for the monthly injectable formulation of Risperidone-ISM. Press release, July 11, 2011 (http://www.rovi.es/otros/89.pdf)

<sup>(3)</sup> Farré M. et al. A clinical trial to evaluate the pharmacokinetics, safety and tolerability of single doses of risperidone with the novel long-acting injectable technology ISM<sup>®</sup> in healthy volunteers. Eur Arch Psychiatry Clin Neurosci 2011; 261 (Suppl 1): S57.

Further Phase I/II studies are planned to start by the second half of 2012, which should allow to progress into Phase III trials by first half of 2014. On the other hand, this study has also served as "proof of concept" for validating ISM technology for the development of other candidates, such as other second generation antipsychotics like olanzapine or paliperidone, which are already on advance preclinical development.

• Letrozole-ISM<sup>®</sup>: ROVI is also dedicating its efforts for the development of a novel formulation for a quarterly injection of a well-recognised aromatase inhibitor, letrozole. The project is already in preclinical phase under animal testing. Letrozole is currently considered as a key therapy for the treatment of the hormone-dependent breast cancer and the ISM technology may provide better compliance and additional benefits to those patients who are suffering from this type of tumour.

	1.3. Pipeline: ISM <sup>™</sup> (		
Platform	Product	Potential indication	Current situation
			Pre-Clinical I II III
ISM	Risperidone, monthly	Schizophrenia	
	Olanzapine, monthly	Schizophrenia	
	Paliperidone, monthly	Schizophrenia	
	Letrozole, quaterly	Breast Cancer	

#### 2. Glycomics

The extracellular matrix in animal tissues is a medium in which there is intense intercellular communication. This communication takes place through recognition phenomena between biomolecules which, unlike the intracellular interactions, take place in an unconfined medium implying notable requirements in terms of selectivity and specificity. In this context, it is important to highlight the essential role played by carbohydrates as this is the type of biomolecule with the greatest capacity for structural diversity and therefore for transmitting information. For this reason, the new term of glycomics has recently been coined as an innovative solution for seeking out carbohydrates with new activities. Glycomics comprises the study and characterization of the sugars making up a cell.

Glycosaminoglycans (GAGs) constitute the main component in the proteoglycans present in the extracellular matrix. These polysaccharides, apart from their well-known role in the regulation of blood clotting,



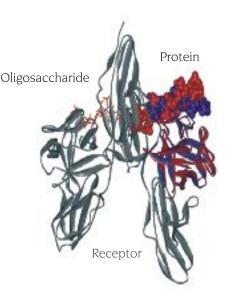
are involved in the control of a large number of cell signalling processes, including in particular processes for cell growth, differentiation, proliferation, immune response and inflammation. In order to exercise these functions, GAGs have to interact, more or less specifically, with numerous proteins taking part in the activation or inhibition of the corresponding signalling cascade. Glycomics studies provide very valuable information in this sense, as they allow determination of the receptors taking part in the interaction with each type of GAG.

> Glycomics comprises the study and characterization of the sugars making up a cell.

#### 2.1. Clinical research: glycomics

The degree of specialization achieved in this area allows consideration of the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products and other glycosaminoglycans, based on both anticoagulant and non-anticoagulant activities.

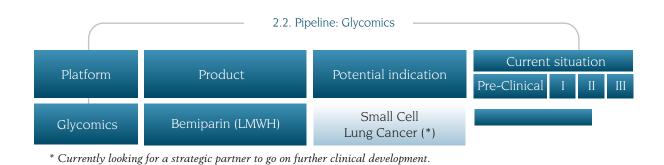
In October 2011, ROVI announced<sup>4</sup> the presentation of the results of the final analysis of the "ABEL" clinical trial (Adjuvant Bemiparin Evaluation study in small cell Lung



cancer) during the XIII National Congress of the Spanish Society of Medical Oncology. The study was aimed to assess the effectiveness and safety of Bemiparin (3,500 IU/day for 26 weeks) in patients with limited small cell lung cancer who are receiving standard anti-tumour treatment (platinum-based chemotherapy and radiotherapy<sup>5</sup>).

According to the data analysis from a total of 39 patients with limited stage disease of small cell lung cancer (after ending the inclusion of new patients because of a slow recruitment rate), it was shown that the disease progression-free survival time (the primary outcome of the trial) increased by 1.5-fold, and the overall survival time increased by 3.3-fold, in the group of patients who received Bemiparin, compared to the control group without Bemiparin, with no rise in the incidence of haemorrhage<sup>6</sup>.

In the light of these results, and taking into consideration the fact that the time and resources needed to continue with the development of Bemiparin for this new therapeutic area are significant, ROVI has decided to look for a partner that specialises in oncology, with the appropriate experience and resources for undertaking the clinical development with sufficient guarantees.



<sup>(4)</sup> Laboratorios Farmacéuticos ROVI S.A. The results of the ABEL clinical trial suggest that Bemiparin could be beneficial against small cell lung cancer. Press release, October 19, 2011. http://www.rovi.es/ficheros/120i.pdf

(5) Phase II study # NCT00324558. http://clinicaltrials.gov/ct/show/NCT00324558?order=2.

<sup>(6)</sup> B. Massuti, et al. Phase II, randomized trial of bemiparin associated to chemotherapy in small cell lung cáncer: Final results from ABEL study. Oral communication. XIII National Congress of the Spanish Society of Medical Oncology (Málaga, October 19-21, 2011).

## Activities report International

Since 2001 when approval was obtained to market Bemiparin in the leading European markets, thanks to the first mutual recognition procedure in the United Kingdom, Italy, Austria, Greece, Ireland and Portugal, ROVI has been unstoppable in its efforts to extend the presence of Bemiparin through the international community and share its benefits with doctors and patients all over the world.

Since then, and due to ROVI's dedication and its strategy of opting for international trade, Bemiparin has extended its presence, whether in pre-registration, registration or marketing stage, to a total of 82 countries thanks to the strategic alliance established with our 19 international partners. ROVI has achieved distribution agreements with highly entrepreneurial pharmaceutical companies that are strongly committed to health such as: Menarini in Central America and Argentina and via its subsidiary Berlín-Chemie, in Central and Eastern Europe and in CIS countries; Sigma-Tau in Italy; Gerot Lannach in Austria; Vianex in Greece; Dem Ilac in Turkey, Hikma in the Middle East and North Africa; Elder Pharmaceuticals in India; Aspen Pharmacare in South Africa; and UCB in Mexico.

The successful conclusion of a new mutual recognition procedure in 8 Eastern European countries, allowed us in 2006 and 2007 to introduce Bemiparin into new European markets such as the Czech Republic, Hungary, Slovakia, Poland, the Baltic States (Lithuania, Latvia and Estonia), which in 2008 were joined by Ukraine and Bulgaria and finally Slovenia in 2009.

2008, 2009 and 2010 were very active years for Bemiparin internationally, with the incorporation of new international partners (Apsen in Brazil, Laboratorios Bagó in Bolivia, Peru and Ecuador, Haji Medicine Co. in Pakistan,



PT Dexa Medica in Indonesia, and Iberma in Morocco) and new launches in Turkey, Ukraine, Kuwait, Yemen, Algeria, Venezuela, Bulgaria, Slovenia, Colombia and South Korea, Morocco, Chile, Georgia and Moldavia.

Year 2011 has special interest due to the new distribution agreements signed with UCB in Mexico, Laboratorios Biopas in Venezuela and CSC Angellini in Romania, while the year also saw the launch of Bemiparin in Russia, Belarus, Bolivia and Bahrain.

ROVI has reached distribution agreements with pharmaceutical companies of high enterprising character.

In 2012, we expect to consolidate the international expansion of Bemiparin, with launches into markets as important as Mexico, Brasil, China, South Africa and Romania which combined with the entry into other



markets such as Saudi Arabia, Sudan, Syria, Pakistan, Oman, Iraq, Ecuador and Bosnia and Herzegovina will clearly contribute to significant progress in the globalization of our innovative second generation molecule.

Bemiparin has positioned itself as one of the leading therapeutic proposals to prevent and treat venous thromboembolic disease in the 46 countries including Spain where it is currently marketed.

Bemiparina has extended his presence to a total of 82 countries.

In terms of the activities carried out this year for the international scientific community, we should highlight the participation of Bemiparin in the second edition of the International Congress of Hip Arthroscopy and Arthroplasty in Santander, Spain in March, which has become a leading international event, where the latest techniques for these type of surgeries are presented. Bemiparin was present in this congress with a stand in the exhibition area. Likewise, ROVI participated in the XII edition of the EFORT (European Federation of National Associations of Orthopedics and Traumatology) Congress in June focused on orthopedic surgery, and in which Bemiparin actively participated with a stand in the exhibition area, a meeting point for our international partners and their doctors.

Furthermore, we supported our partner in Central America, Menarini, in the organization of the Second Conference of Multidisciplinary Experts in Thromboprophylaxis in Panama City with the participation of opinion leaders from this region. In India, together with our partner Elder Pharmaceuticals we organized several Continuous Medical Education meetings covering the prevention and treatment of venous thromboembolic disease in different cities with the participation of more than 100 doctors from this country. 2011 concluded with the third edition of the prestigious "Anti-Thrombosis Masterclass" held in Berlin, Germany. This is the most outstanding conference in which Bemiparin is present and in this last edition had an audience of 120 of the most significant international opinion leaders.

The development of our web page www.bemiparin.com in 2008, with exclusive access for international partners, and the launch in 2009 of another portal called Bemimed ("Bemiparin International Medical Information"), has allowed us to position the molecule in a digital and interactive environment, making use of new technologies to promote not only the exchange of promotional and scientific information about our molecule with our international partners but also the spreading of the latest advances on venous thromboembolic disease and the use of Bemiparin with our scientific community. During 2011, the private portal for our partners and doctors experienced a significant increase in terms of registered users, mainly due to the constant updates provided on scientific publications and information about our international activities for healthcare professionals.

In 2011, we have been present in the most important congresses and international forums of the sector.

## Activities report Products

#### CARDIOVASCULAR

### Hibor®

Venous thromboembolic disease (VTD) includes deepvein thrombosis in the lower or upper limbs (DVT) and pulmonary embolism (PE). VTD is a serious and potentially fatal process, characterized by the formation of a fibrin clot, thrombosis, inside the veins of the deep vein system, with all the consequences of the evolution of venous thromboses, including growth, progression and fragmentation. In the latter case, some of the fragments may break loose and reach the lung, causing PE.

In Spain the data handled indicate around 65,000 cases of DVT and 25,000 of PE per year, giving a total incidence of 90,000 cases per year (Thromb Haemost 2000, 2001 and 2005).

Hibor (Bemiparin) is a low molecular weight heparin ("LMWH") indicated for preventing and treating thromboembolic disease (TED), both in surgical and medical patients, and for the intense and long-term treatment of patients who have suffered a TED process.

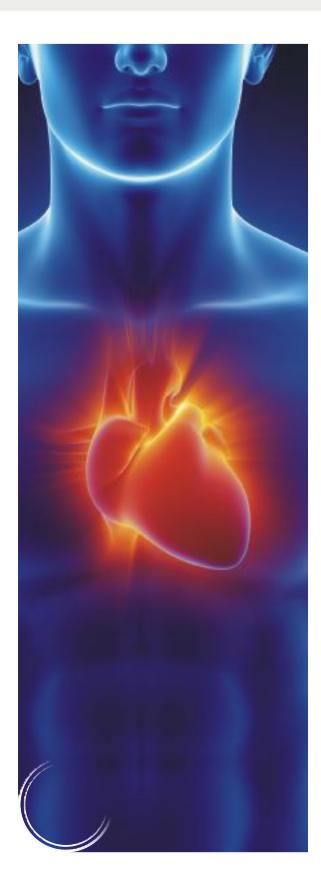
It is also indicated for preventing coagulation in the extracorporeal circuit during haemodialysis.

Hibor (Bemiparin) has consolidated its position in the market for anti-thrombosis drugs as the second most-sold LMWH in Spain (IMS, December 2011).



It has a significant international presence. The product has been approved in 46 countries in 4 continents, has been approved and is pending marketing in another 5 countries, and is in the approval process in a further 18 countries.

### Corlentor®



Corlentor (ivabradine) is indicated for:

 Treatment of coronary artery disease: symptomatic treatment of chronic stable angina pectoris in adults with coronary artery disease with normal sinus rhythm.

Ivabradine is indicated:

- in adults unable to tolerate or with a contraindication to the use of beta-blockers;
- or in combination with beta-blockers in patients inadequately controlled with an optimal betablockers dose and whose heart rate is >60 bpm (beats per minute).
- Treatment of chronic heart failure.

Ivabradine is indicated in patients with chronic heart failure in NYHA II to IV with systolic dysfunction, in patients in sinus rhythm with heart rate 75 bpm, in combination with standard therapy including beta-blocker therapy or when betablocker therapy is contraindicated or not tolerated.

Corlentor is supplied in film-coated tablets containing 5 mg and 7.5 mg of ivabradine. It is a product developed by Les Laboratories Servier and marketed in Spain by Laboratorios Farmacéuticos Rovi, S.A.

Stable angina is a clinical syndrome characterized by pain in the chest, jaw, shoulders, back or arms, typically arising after an effort or emotional stress.

The epidemiology data on stable angina in Spain, gathered in an analysis carried out by the Ministry of Health and Consumer Affairs, in 2001, on the situation of ischaemic cardiopathy in this country, estimate its prevalence at between 600,000 and 900,000 patients.

Corlentor has received various awards since its launch, and in 2008 was awarded the prestigious Galien Prize for the Best Medicine of 2008 in Spain.

### Ameride®

Ameride is indicated for the treatment of hypertension (high blood pressure) especially in patients with low potassium levels, edema with a coronary origin (swelling of ankles, feet or legs, due to retention of water), and ascites (accumulation of water in the abdomen) due to a cirrhosis (liver disease).

Ameride is a combination of amiloride hydrochloride and hydrochlororthiazide. The component amiloride that is contained in Ameride belongs to the antikaliuretic type of agents (potassuim conserving); amiloride is also a weak diuretic. The component hydrochlororthiazide in Ameride belongs to the diuretic (thiazide) group of drugs. Ameride acts by making the kidneys eliminate more water and salt and retain more potassium. This helps to reduce hypertension and some forms of edema, while at the same time helping to maintain normal levels of potassium in the blood.

CARDIOVASCULAR



#### CARDIOVASCULAR

### Prinivil<sup>®</sup> and Prinivil<sup>®</sup> Plus

Prinivil contains lisinopril and belongs to a group of drugs which are known as inhibitors of the angiotensin converting enzyme (ACE inhibitors). Prinivil is indicated for the treatment of hypertension (high blood pressure), for the treatment of symptomatic heart failure, the short term treatment of acute myocardial infarction, and the treatment of complications related to the type II diabetes kidney in patients with hypertension. Prinivil Plus contains two different active principles: (i) the component lisinopril, a drug which belongs to the group of ACE inhibitors, and (ii) the component hydrochlorothiazide, which belongs to the diuretic group. Lisinopril dilates blood vessels and facilitates the pumping of blood from the heart to all parts of the body. Hydrochlorothiazide enables the kidneys to let pass more water and salt. Combined, both components work to reduce high blood pressure.



#### CARDIOVASCULAR

PRIMARY CARE

### Vytorin®

#### Hypercholesterolaemia

Vytorin is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and nonfamilial) hypercholesterolaemia or mixed hyperlipidaemia where use of a combination product is appropriate:

- patients not appropriately controlled with a statin alone; and
- patients already treated with a statin and ezetimibe.

Vytorin contains ezetimibe and simvastatin. Simvastatin (20-40 mg) has been shown to reduce the frequency of cardiovascular events. A beneficial effect of Vytorin or ezetimibe on cardiovascular morbidity and mortality has not yet been demonstrated.

#### Homozygous familial hypercholesterolaemia (HoFH)

Vytorin is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g. low density lipoprotein [LDL] apheresis).

Vytorin is marketed in tablets containing 10 mg of ezetimibe and 20 mg of simvastatin and in tablets containing 10 mg of ezetimibe and 40 mg of simvastatin. It is a product developed by Merck Sharp & Dohme and marketed in Spain by ROVI since 2011.

CARDIOVASCULAR

PRIMARY CARE

### Absorcol®

#### Primary hypercholesterolaemia

Absorcol, co-administered with a HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia who are not appropriately controlled with a statin alone.

Absorcol monotherapy is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia in whom a statin is considered inappropriate or is not tolerated.

#### Homozygous familial hypercholesterolaemia (HoFH)

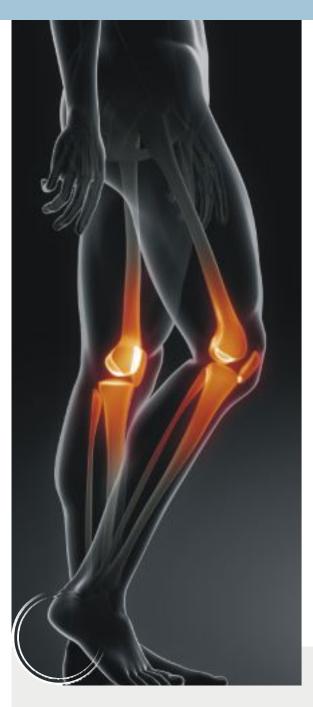
Absorcol, co-administered with a statin, is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive other adjunctive treatments (e.g., LDL apheresis).

#### Homozygous sitosterolaemia (phytosterolaemia)

Absorcol is indicated as adjunctive therapy to diet for use in patients with homozygous familial sitosterolaemia.

A beneficial effect of Absorcol on cardiovascular morbidity and mortality has not yet been demonstrated.

Absorcol is supplied in tablets containing 10 mg of ezetimibe. It is a product developed by Merck Sharp & Dohme and marketed in Spain by ROVI since 2011.



#### OSTEOARTICULAR

### Osseor®

Osseor, whose main active ingredient is strontium ranelate, is indicated for the treatment of osteoporosis in postmenopausal women in order to decrease the risk of spinal or hip fractures. It is the result of research at Les Laboratoires Servier and has been marketed by ROVI since 2005.

Osteoporosis is a skeletal disease characterized by lowered bone resistance that predisposes people to an increased risk of fracture. Of the 3.5 million people who suffer from osteoporosis in Spain, only 18% are diagnosed. Approximately 33% of women aged between 60 and 70 and 66% of women over 80 years of age have osteoporosis. It is calculated that 47% of women may suffer an osteoporotic fracture. (Rev Clin Esp. 2003; 203 (10): 496-506; Rev Clin Esp. 2008; 208 Supl 1:1-24).

The Spanish osteoporosis market involves around 13 million treatments each year, which represented around 321 million euros in 2011. Osseor has a market share by value of around 2.3% (IMS, MAT December 2011).

#### OSTEOARTICULAR

### Bertanel®

Bertanel is a parenteral methotrexate, indicated for:

- active rheumatoid arthritis in adult patients when treatment with disease-modifying antirheumatic drugs (DMADs) is indicated;
- polyarthritic forms of severe active juvenile idiopathic arthritis (JIA), when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate; and
- severe forms of psoriasis vulgaris, particularly of the type in plaques, that cannot be treated adequately

with conventional therapy, such as phototherapy, PUVA and retinoids, and severe psoriatic arthritis.

Bertanel is supplied in prefilled syringes. It is a product that has been developed by EBEWE Pharma and has been marketed by ROVI in Spain since September 2010.

According to data from IMS Health, the subcutaneous metotrexates market amounted to 25 million euros in 2011, a rise of 6.4% compared to the previous year. Bertanel has a market share by value of 7.8% (IMS, MAT December 2011).

#### OSTEOARTICULAR

ROVI Calcium and Vitamin D3 is indicated to correct a combined deficiency of calcium and vitamin D in the elderly, and as vitamin D and calcium supplement, as an adjuvant to specific therapy, for the treatment of osteoporosis in patients with manifest deficiency of combined calcium and vitamin D or a high risk of this deficiency.

### ROVI Calcium and Vitamin D3<sup>®</sup>

In adults, the daily calcium requirement is 1,000 mg while in the elderly and post-menopausal women, it is at least 1,200 mg. Likewise, it is advisable for adults older than 50 to ingest 800-1000 IU/day of vitamin D ("National Osteoporosis Foundation's Updated Recommendations for Calcium and Vitamin D3 Intake", Reviewed October 2008).



#### OSTEOARTICULAR

Glufan®

Glufan is indicated for relieving symptoms of mild to moderate degenerative osteoarthritis.

OSTEOARTICULAR



Cimzia is a PEGylated anti-TNF alpha monoclonal drug (tumor necrosis factor-alpha TNF alpha). Its active principle is certolizumab pegol and it is indicated for the treatment of rheumatoid arthritis.

Cimzia is a UCB product that ROVI has jointly co-promoted in Spain since 2010.

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### Exxiv®

Exxiv is a selective COX-2 inhibitor indicated for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis.

The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.

Exxiv offers different concentrations based on the disease for which symptoms are to be treated. It is supplied in filmcoated tablets containing 60 mg (indicated for osteoarthritis), 90 mg (for rheumatoid arthritis and ankylosing spondylitis), and 120 mg of etoricoxib (acute gouty arthritis, only for 8 days of treatment).

It is a product developed by Merck Sharp & Dohme and marketed in Spain by ROVI since 2008.

#### PAIN RELIEF

#### **CENTRAL NERVOUS SYSTEM**

### Thymanax®

Tryptizol®

Thymanax is an antidepressant which is indicated for adults with major depressive episodes. It is the result of research at Les Laboratoires Servier and has been marketed by ROVI since 2010.

Depression is currently one of the main challenges of Spanish public health, and is the cause of significant suffering for an increasing number of patients and also for their families, with a major impact on their quality of life. In addition, depression is accompanied by high socioeconomic costs, due to its consequences in the social and labour areas. The WHO (World Health Organisation) calculates that in 2020 major depression will be the second largest cause of disability, behind cardiovascular diseases.

**CENTRAL NERVOUS SYSTEM** 

Tryptizol belongs to a group of drugs known as tricyclic antidepressants and contains amitryptiline.

It is indicated for the treatment of depression, nocturnal enuresis (involuntary release of urine in sleep), and chronic neuropathic pain (pain caused by damage to the nervous system).



# Hospital division



### Sonovue®

Sonovue, marketed by ROVI under a license from Bracco Imaging S.p.A., is a medicinal product for diagnostic use only, used in order to enhance the ultrasound imaging of the echogenicity of the blood, which results in an improved signal to noise ratio.

Sonovue is indicated for:

• Echocardiography. Sonovue is a transpulmonary echocardiographic contrast agent for use in patients with suspected or established cardiovascular disease to provide opacification of cardiac chambers and enhance left ventricular endocardial border delineation.

IMAGING DIAGNOSTIC AREA Imaging contrast media

- **Doppler of macrovasculature**. Sonovue increases the accuracy in detection or exclusion of abnormalities in cerebral arteries and extracranial carotid of peripheral arteries by improving the Doppler signal to noise ratio. Sonovue increases the quality of the Doppler flow image and the duration of clinically useful signal enhancement in portal vein assessment.
- **Doppler of microvasculature**. Sonovue improves the display of the vascularity of liver and breast lesions during Doppler sonography, leading to more specific lesion characterization.

#### IMAGING DIAGNOSTIC AREA Imaging contrast media

lomeron and lopamiro are two nonionic iodinated radiographic contrast media for diagnosis by computerized tomography or X-ray diagnostic techniques. These two products are marketed by ROVI, under licenses from Bracco Imaging S.p.A.

Presentations:

- Iomeron: from 200 mg/ml to 400 mg/ml concentration, in glass bottles quantities from 50 to 500 ml.
- Iopamiro: 300 mg/ml and 370 mg/ml concentration, in glass bottles quantities from 30 to 100 ml.

### Iomeron<sup>®</sup> and Iopamiro<sup>®</sup>



IMAGING DIAGNOSTIC AREA Imaging contrast media

Multihance and Prohance, both marketed by ROVI under a license from Bracco Imaging S.p.A.

Multihance is a paramagnetic contrast agent for use in diagnostic magnetic resonance imaging (MRI) indicated for:

- MRI of the liver for the detection of focal liver lesions in patients with known or suspected primary liver cancer (eg. hepatocellular carcinoma) or metastatic disease.
- MRI of the brain and spine where it improves the detection of lesions and provides diagnostic information additional to that obtained with unenhanced MRI.
- Contrast-enhanced MRI angiography where it improves the diagnostic accuracy for detecting

### Multihance<sup>®</sup> and Prohance<sup>®</sup>

clinically significant steno-occlusive vascular disease in patients with suspected or known vascular disease of the abdominal or peripheral arteries.

Multihance is commercialized in 10, 15 and 20 ml glass vials.

Prohance, using Magnetic Resonance Imaging (MRI), provides contrast enhancement of the brain, spine and surrounding tissues resulting in improved visualization (compared with unenhanced MRI) of lesions with abnormal vascularity or those thought to cause a disruption of the normal blood-brain barrier. Prohance can also be used for whole body MRI including the head, neck, liver, breast, muscoloskeletal system and soft tissue pathologies.

Prohance is commercialized in 10, 15, 20 and 50 ml glass vials and 10 and 17 ml pre-filled glass syringes.

### EmpowerCTA<sup>®</sup> and EmpowerMR<sup>®</sup>

ROVI commercializes EmpowerCTA and EmpowerMR injectors under a license from ACIST Medical Systems.

EmpowerCTA is a dual-syringe, fixed-rate contrast injector for computed tomography procedures.

The EmpowerMR Hydraulic Contrast Injection System is used for MR procedures.

IMAGING DIAGNOSTIC AREA Contrast injection systems



HAEMODIALYSIS AREA Low Molecular Weight Heparin

### Hepadren®

Hepadren is a low molecular weight heparin targeted especially at the nephrology area, for the prevention of clotting in the extracorporeal circuit during haemodialysis.





#### VASCULAR ACCESS AREA

### Fibrilin®

Fibrilin is a ROVI health-care product that has been marketed since November, 2001. It is used for catheter maintenance, preventing the accumulation of fibrin in intravenous peripheral and central catheters, thus avoiding blockage and infection of the catheter.

#### **ORPHAN MEDICINES**

Siklos is a drug indicated for the prevention of painful and recurrent blood vessels crisis, such as the acute thoracic syndrome in children and adults who suffer from symptomatic drepanocytosis anaemia.

Siklos is supplied in film-coated tablets, with three slots on each side, containing 1,000 mg of hydroxycarbamide. The tablet can be divided into four equal parts. Siklos®

As the drepanocytosis anaemia is a rare disease in Europe, Siklos is considered an orphan medicine by the European Medicines Agency.

## Vaccines

### Pneumovax<sup>®</sup> 23

Pneumovax 23 vaccine vial is indicated for active immunization against illness caused by the seroypes of pneumococci included in the vaccine. The product has been marketed by ROVI from 2009 under a co-marketing agreement with Sanofi Pasteur MSD.

Pneumovax 23 is prepared using purified pneumococcal capsular polysaccharide antigens, derived from the 23 serotypes which represent about 90% of the types of the pneumococcal invading disease.

Pneumococcal illness is caused by streptococcus pneumoniae and is a global health problem. In Spain, streptococcus pneumoniae is responsible for 20-30% of all cases of pneumonia, of which 5-20% develop bacteremia (Vila Córcoles A. and colleagues. Effectiveness of the anti-pneumococcal vaccine in patients older than 65. Medifam 2003; 13(4):297-304).



### Alentia Biotech vaccines



Alentia Biotech, a joint venture in which Grupo Ferrer Internacional, S.A. and Laboratorios Farmacéuticos Rovi, S.A. participate, plans to construct a manufacturing plant in Granada to produce flu vaccines in the Spanish market.

On the 26th of September, Alentia Biotech announced that it has signed an agreement with Novartis Vaccines & Diagnostics for the transfer and granting of a licence of use for technology, belonging to the latter, for the production of vaccines against seasonal and pandemic flu mainly for Spain and Portugal.

Through these agreements, Alentia Biotech will commence the construction of a production plant in Granada (Spain). Likewise, during the construction of the production plant, Alentia Biotech will be entitled to market seasonal flu vaccines under a co-marketing regime with Novartis Vaccines & Diagnostics for an estimated five-year period.

## OTC

### EnerZona®

Enerzona Omega 3 Rx is a highly-concentrated and purified fish-oil supplement that allows us to provide an effective dose in a simple way while avoiding the pollutants in fish.

There are also a wide range of sweet and savoury products to help us maintain the 40-30-30 balance, so as to be able to follow the Zone Diet easily and maximize the benefits obtained. The sweet products include fructose, chocolate biscuits, coconut or oatcakes; snacks are available in coconut, chocolate, yoghurt, orange, vanilla and cheese cake flavours; instant meals can be strawberry, cappuccino or chocolate flavour. The savoury options include snacks with a black olive or Mediterranean flavours, soy chips and mushroom and vegetable creams.

Enerzone Whey 90% and Enerzone Soy 90% are pure sources of protein.



### Perspirex®

In any situation, including long working days, stress, crowds, events and special occasions, very uncomfortable episodes of sweating can occur.

Perspirex is an antiperspirant treatment developed to control excessive sweating from the armpits. The active substances it contains reduce sweating, physically speaking a minor problem but one which produces a serious social impact.

Perspirex is the market leader in this sector. There is also a presentation for the hands and feet.



# 

# Dentimelo®

Dentimelo is a low molecular weight hyaluronic acid which protects oral mucosa.

The low molecular weight hyaluronic acid, with filmforming properties, promotes the process of skin reepithelialization. Dentimelo is indicated to promote the physiological process of repair of oral mucosal lesions and gums, whatever their origin, in a natural way.

There are two presentations, gel and fluid.

# Coldpack®

ColdPack is a cold bag, used for local application, which mitigates pain and relieves the nerve endings of the affected area. It also reduces inflammation alleviating the sharp sensation experienced with headaches or inflammations due to injures. ColdPack can also be used as a hot bag to relieve other pains.



# Activities report Portugal

ROVI Portugal was established in April 1999, for the marketing of the Italian company Bracco's contrast media already sold in Spain.



is enjoying solid yearly growth rates and is outperforming the market.

ROVI and Bracco are now both very successful brands in Portugal. ROVI has increased and consolidated its stake in the contrast media market, leveraging its knowledge of hospital pharmacies and radiologists.

In 2007, we launched in Portugal the first product developed by ROVI, Fibrilin $^{\circ}$ , which received an excellent response from the market.

ROVI Portugal is enjoying solid yearly growth rates and is outperforming the market, despite difficult economic and political conditions.

Specialization in the hospital market, more dynamic commercial strategies and new products have contributed to the growth of ROVI and to its excellent reputation in a market that is particularly important to the Company.



# Activities report Contract manufacturing

ROVI offers contract manufacturing services in a wide range of pharmaceutical forms, including pre-filled syringes, vials, suppositories and tablets through our two contract manufacturing sites: ROVI CM & ROVI Alcalá.

Our main characteristics are:

- quality in products and service;
- an independent company with significant production capacity;
- flexible, committed and totally transparent with our clients;
- confidentiality at the core of how we operate; and
- our commitment to meeting the requirements of clients.

From one single company, ROVI provides the full range of services, from the development of a project to the final

release of a product, including preliminary clinical trials, stability studies, and physical-chemical and microbiological analyses, with the corresponding savings in time and money for our clients.

The flexibility and versatility of ROVI allow us to offer customers all or any of the many services involved in the manufacturing of a pharmaceutical product; a personalized menu for the specific needs of each client.

ROVI is currently one of the largest manufacturers of prefilled syringes worldwide, with total yearly capacity of 180 million prefilled syringes. The total yearly capacity of vials is 40 million units and 150 million units of suppositories. ROVI also owns one of the largest FDA approved plants for solid forms in Europe with annual capacity for 3,000 million tablets.



# ROVI CM: Prefilled syringes and vials



With more than 15 years of experience, ROVI CM specializes in filling and packaging parenteral solutions in prefilled SCF syringes from 0.5ml to 20ml (filled from 0.2 ml to 20ml) and vials from 2ml to 7ml.

#### Aseptic filling and terminal sterilisation.

Syringes and vials are filled in aseptic conditions in sterile areas. If needed, terminal sterilisation can be performed in a brand new counter-pressure autoclave.

#### Safety devices.

An increasing number of countries are implementing legislation that requires the use of integrated safety devices, in order to minimize the risk of accidental needle stick injury.

ROVI CM offers the possibility of adding safety devices to the preloaded syringes, using new fully automatic equipment that can handle up to 21,000 units per hour.

#### Diluents (Syringes with Water for Injection).

ROVI CM provides its clients with syringes that are prefilled with Water for Injection, in different sizes and volumes with a 3 year expiry date.

To facilitate the registration process, ROVI CM provides its clients, at no cost, with the CTD module 3 ("Common Technical Dossier") and the DMF (Drug Master File).

The Water for Injection is produced according to the requirements of US and European Pharmacopoeia.

The types of syringes and volumes of WFI are as follows:

- Iml standard syringes filled with 0.5ml of Water for Injection;
- 1.25ml syringes filled with 1ml of Water for Injection;
- 3ml syringes filled with 2ml of Water for Injection;
- 10ml syringes filled with 5ml and 10ml of Water for Injection; and
- 20ml syringes filled with 15ml and 20ml of Water for Injection.

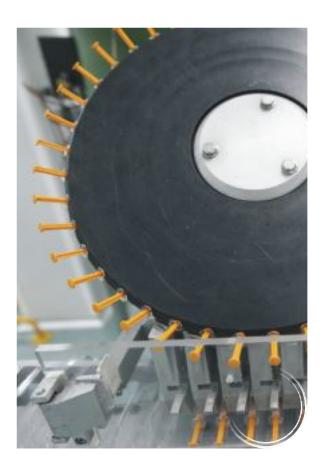
#### Quality

A new laboratory building was built in 2005 and includes two independent laboratories (microbiology and chemistry), enabling 24-hour production.

The plant is approved by the European Authorities and also by the authorities of South Korea, Brazil and the countries of the Gulf, and it is ISO (9001, 14001, OSHAS) certified.

#### Suppositories

ROVI CM is also a specialist in the manufacturing and packaging of suppositories in aluminum blister packs.



# ROVI Alcalá: Solid forms

In the agreement reached with Merck Sharp & Dhome (MSD), ROVI acquired in April 2010 the manufacturing and packaging operations of the MSD facility in Alcalá de Henares. This plant has a long tradition of manufacturing excellence in pharmaceutical products and uses state of the art technology - Roller Compaction - for manufactur-ing oral formulations.

#### Technology

In an 83,000m<sup>2</sup> terrain, facilities include:

- Formulation Areas:
  - Dry granulation: highly competitive costs thanks to our high capacity Roller Compactor;
  - Wet granulation (High Shear and Low Shear), including fluid bed drying, milling and ribbon blending;
  - Planetary mixers;
  - Different compression bays for direct compression and granulation compression; and
  - Film coating is also available.
- Packaging Areas:
  - Different high speed blistering lines, flexible blister lines and flexible semiautomatic lines; and
  - Cartoning, labelling, marking, overwrapping and casepacking capability for every packaging line.
     Every line is equipped with high tech vision system capability.

A complete service: production - testing - packaging and storage:

- High total and free capacity available to meet medium to very large production requirements (global capacity 3,000 million tablets/year);
- From batches of 100 kg up to batches of 1,000 kg;
- Flexible and/or large volume packaging available to comply with customer needs; and
- Large size warehouse (8,000 pallets) which include a cold room (2 to 8 C°) of 400 pallets.



#### Quality

A brand new quality laboratory was built in 2005 in a separate building (4,600 m2) and includes a microbiology lab, a chemistry lab and quality assurance offices.

In order to provide access to all markets, ROVI Alcalá is GMP and FDA approved. We also hold Japanese, Mexican, Brazilian and Gulf Countries approval.



# Clinical trials

Complying with both American and European quality standards, ROVI offers competitive technical support from the standpoints of cost, flexibility and reliability.

ROVI offers a wide range of services for the performance of clinical trials, product preparation and filling, labelling, packaging and logistics, always with the most rigorous quality standards. The machinery used is the same as for an industrial-scale batch, so it complies with the latest European regulations on clinical trials.

ROVI team of experts can advise customers on all aspects from manufacturing to the design of packaging materials to ensure time constraints are met.

## For ROVI, every project is the most important, no matter its size.

# Product development

ROVI can provide advice on the best strategy to follow, from the introduction of a new product to its pre-clinical technical development for a commercial batch. In other words, we are involved in the project management and feasibility studies, launch and preproduction strategies, technological transfer and registration issues.

All of this ensures that the new product complies with all legal requirements and can be launched appropriately in the right place at the right time, with sufficient quantity of products.

# **Co-Development Projects**

In order to increase the manufacturing of both facilities (ROVI CM and ROVI Alcalá), Co-Development services (initial model) are offered:

- Partner chooses and provides the API (active principle);
- **2.** ROVI offers from pre/formulation, scale up, stability batches, regulatory batches, bioequivalence studies if necessary, dossier compilation to manufacturing industrial batches; and

3. Licensing: directly through partner or out-licensing.

We are committed to ensure a personalized service to each partner so we can adapt to variations in our initial Co-development model.

The model proposed is a virtual joint venture with a costprofit sharing approach.

## New agreements

In June 2009, the Company signed a protocol of intentions with the Ministry of Health and Social Policy and the Regional Ministries of Innovation, Science and Enterprise, and Health of the Government of Andalusia for the development of a centre for the production of vaccines for seasonal and pandemic flu in Spain. For the development of this project, Alentia Biotech, a joint venture of Ferrer and ROVI, was created. In September 2011, Alentia Biotech signed an agreement with Novartis Vaccines in order to use its technology for the production of flu vaccines for Spain and Portugal. The estimated investment for the construction and start of operations is around 92 million euros. The plant will have annual manufacturing capacity of 10 million doses of seasonal flu vaccines, and 30 million doses of vaccines for pandemic flu. The project would be implemented with the collaboration of the Department of Economy, Innovation and Science of the Regional Government of Andalusia and the Ministry of Health, Social Policy and Equality of the Spanish Government and likewise has the backing of the Ministry of Science and Innovation.



# Management report

ROVI reports an operating revenues growth of 16% and confirms its full year guidance



Operating revenues increased by 16% to 184.7 million euros in 2011, driven by the strength of the specialty pharmaceutical business, where sales rose 13%, and of the toll manufacturing business which grew by 28% in 2011.

2011 operating revenues guidance, upgraded from low double digit to mid teens on November 8, 2011, achieved. Forecast operating revenues growth for 2012 is from high single digit to low double digit.

Sales of Bemiparin increased by 15% to 50.5 million euros and sales of Corlentor and Osseor, from Servier, grew by 40% and 7% respectively in 2011. Sales of Thymanax, an innovative antidepressant from Servier that ROVI launched in March 2010, increased by 2.7 times to 8.6 million euros in 2011.

In January 2011, ROVI started the marketing of Absorcol<sup>®</sup>, whose active principle is ezetimibe, and Vytorin<sup>®</sup>, which combines two active principles, ezetimibe and simvastatin, the first of the five licenses of Merck Sharp & Dohme (MSD), in Spain. Sales of Absorcol<sup>®</sup> and Vytorin<sup>®</sup> reached 5.7 million euros in 2011.



In the second quarter of 2011, Fitoladius<sup>®</sup> product was sold to a third part. This sale contributed with revenues of 5.6 million euros in 2011.

Excluding the impact of the one-off profit of 11.8 million euros, registered in the second quarter of 2010, caused by the difference between the fair value and the purchase price of the Frosst Ibérica assets, EBITDA increased by 33% in 2011. EBITDA decreased by 20% to 23.7 million euros in 2011, compared to the previous year, as a result of the impact of the one-off profit of 11.8 million euros registered in the second quarter of 2010.

Excluding te impact of the Fitoladius sale and the impact of the measures to reduce the pharmaceutical expenditure, EBITDA increased by around 22% in 2011.

Net pofit decreased by 26% to 18.1 million euros in 2011, impacted by the same factors as EBITDA. Recurrent net profit rose 42% in 2011, above the single digit growth guidance provided for 2011.

ROVI will propose to the Shareholders General Meeting a dividend of 0.1269 euros per share on 2011 earnings. This proposed dividend would imply the pay-out of 35% of consolidated net profit for 2011.



Our pillars of growth: the specialty pharmaceutical area and the toll manufacturing area.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that "in 2011, we reached an excellent 16% operating revenues growth driven by the strength of two of our pillars of growth, our specialty pharmaceutical area and our toll manufacturing area. We continued to record sales growth in our specialty pharmaceutical business despite the negative impact related to the measures introduced by the government in the second half of 2010 for the rationalisation of the pharmaceutical expenditure, estimated at 8 million euros on 2011 sales. Our young portfolio has protected us from the latest governmental measures, which were effective from November 2011, and we expect to have an impact of less than 1 million euros on 2012 sales. Once again Bemiparin led the growth with a 15% increase in sales. Bemiparin sales in Spain rose 14% and outside Spain grew by 18%, highlighting the continued internationalisation of our flagship product as one of the Company's growth engines in the medium term. Furthermore, the agreement with MSD allows us to strengthen our toll manufacturing area, as we have already reflected in the 2010 and 2011 results, as well as our specialty pharmaceutical area, as we have shown with the launch, in January 2011, of Vytorin and Absorcol, the first of the five licenses from MSD that will contribute to our growth in the coming years. This launch required a significant investment effort in human capital in order to address new prescribers, among them a selection of primary care prescribers. Our investment effort had an impact on 2011 net result but we expect to achieve strong

sales growth and operating leverage in the coming years. In addition, the MSD agreement will allow us to launch four additional new products in the next 10 years, underpinning our belief in the sustainability of the long term outlook for the company. The development of the research and production centre for seasonal and pandemic flu vaccines in Spain, also reflects our commitment to diversify and to reinforce our business model and, together with the MSD agreement, provide us with an excellent opportunity for growth as we maximise the potential of the infrastructure we have built and purchased. We are committed to the flu vaccines business as one of the future growth drivers for the company. ROVI's R&D pipeline continues to hold strong potential to drive the company's growth in future years. We are very excited with the potential of the ISM technology, especially with the Risperidone-ISM<sup>®</sup> project development, whose phase I positive results were announced in July. This gives us the confidence and security to continue, not only with our development of Risperidone ISM, but also with the development of other candidates with which we are already in an advanced pre-clinical phase".

# Financial highlights

€ million	2011	2010	Growth	%Growth	
Operting revenues	184.7	158.6	26.1	16%	
Other income	3.5	1.5	2.0	131%	
Total revenue	188.2	160.1	28.0	17%	
Raw meterials used and changes in inventories	-69.4	-62.8	-6.6	11%	
Gross profit	118.7	97.3	21.4	22%	
% margin	64.3%	61.3%		2.9pp	
R&D expenses	-8.4	-8.5	0.1	-1%	
Other SG&A	-86.6	-71.0	-15.6	22%	
Other income		11.8	-11.8	n.a.	
EBITDA	23.7	29.6	-5.9	-20%	
% margin	12.8%	18.7%		-5.8pp	
EBIT	19.0	26,0	-7.0	-27%	
% margin	10.3%	16.4%		-6.1pp	
Net profit	18.1	24.6	-6.5	-26%	

Note: certain numerical figures included in this document have been rounded. Therefore, discrepancies in tables between totals and the sums of the amounts listed may occur due to such rounding.

# Good performance across the Group

**Operating revenues** increased by 16% to 184.7 million euros in 2011, driven by the strength of the specialty pharmaceutical business, where sales rose 13%, and of the toll

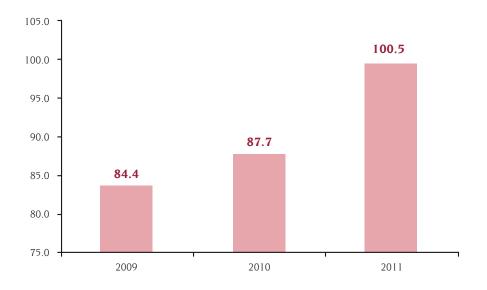
manufacturing business which grew by 28% in 2011.



Sales of **prescription-based pharmaceutical products** rose 15% to 100.5 million euros in 2011. Excluding the impact of the measures to reduce the pharmaceutical



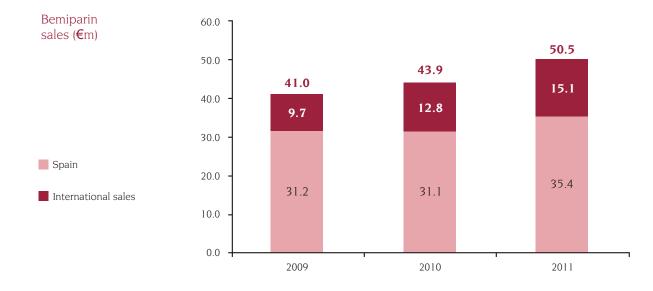
expenditure, sales of prescription-based pharmaceutical products rose around 19% in 2011.



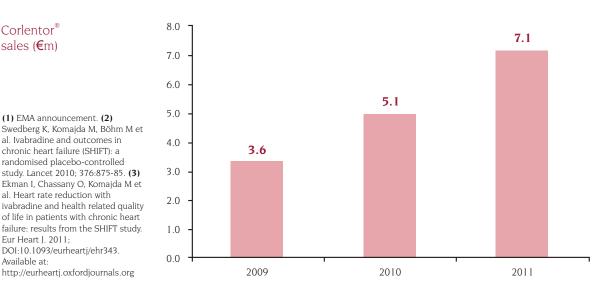
Laboratorios ROVI 2011 Annual Report

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 15% to 50.5 million euros. Sales of Bemiparin in Spain (Hibor<sup>®</sup>) increased by 14% to 35.4 million euros, while international sales rose by 18% from last year supported by the increased presence of

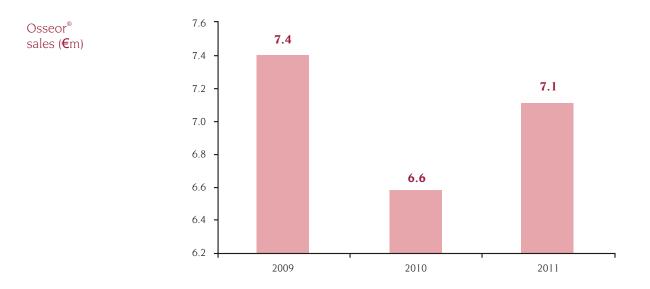
Bemiparin, through strategic alliances, in countries where it was already present, and by the launch of the product in four new countries, Bolivia, Belarus, Russia and Bahrain, during 2011.



Sales of **Corlentor**<sup>®</sup>, a specialty product for stable angina and chronic heart failure<sup>1</sup> from Laboratoires Servier, rose 40% in 2011, to 7.1 million euros. In February 2012, Corlentor<sup>®</sup> has been approved by the European Commission for the treatment of patients with chronic heart failure<sup>1</sup>. The European Commission's decision to authorise this new indication for Corlentor<sup>®</sup> followed the review of data from the SHIfT trial, the largest-ever morbi-mortality study of treatments for chronic heart failure involving more than 6000 patients. It demonstrated that the treatment significantly reduced the risk of death and hospitalisation from heart failure, and improved the quality of life of people living with the disease.<sup>23</sup> This reduction in mortality was highly significant in patients with a heart rate of 75 beats per minute (bpm), or above, for whom Corlentor<sup>®</sup> is now indicated.

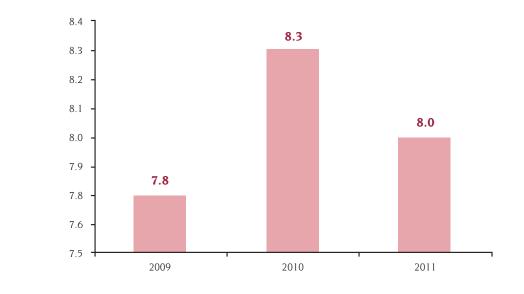


Sales of **Osseor**<sup>®</sup>, a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, increased by 7% in 2011, to 7.1 million euros.



Sales of  $Exxiv^{\text{@}}$ , a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 3% to 8.0 million euros in 2011 mainly due to a slight deceleration of the COX-2 market.





Sales of **Thymanax**<sup>®</sup>, an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for which ROVI has a co-marketing agreement covering Spain, increased by 2.7 times to 8.6 million euros in 2011.



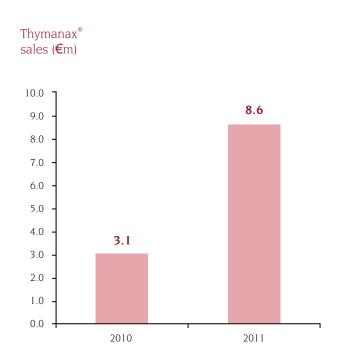
The impact of the measures approved to reduce the pharmaceutical expenditure in 2011 was in line with the impact expected of 8 million euros on 2011 sales, published in the earnings release for the first half of 2010.

On 21st of July of 2011, the Spanish government announced a new measures package to reduce the pharmaceutical expenditure.

(See http://www.msps.es/gabinetePrensa/notaPrensa/ desarrolloNotaPrensa.jsp?id=2165).

The impact of these new measures, which were effective from November 2011, will not be significant for the accounts of the company in 2012. ROVI expects that this impact could be less than 1 million euros in 2012.

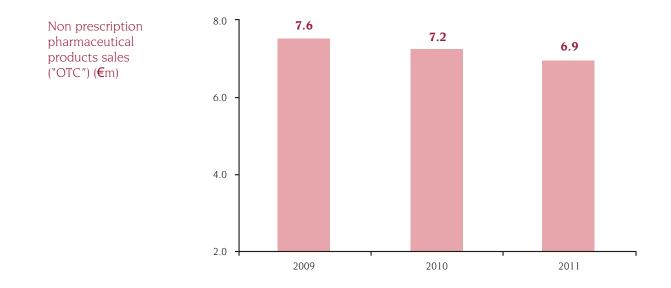
In the second quarter of 2011, **Fitoladius**<sup>®</sup> product was sold to a third part. This sale contributed with revenues of 5.6 million euros in the 2011. This profit was already included in the 2011 operating revenues guidance, published in the earnings release for the nine-month period ended 30 September 2010.



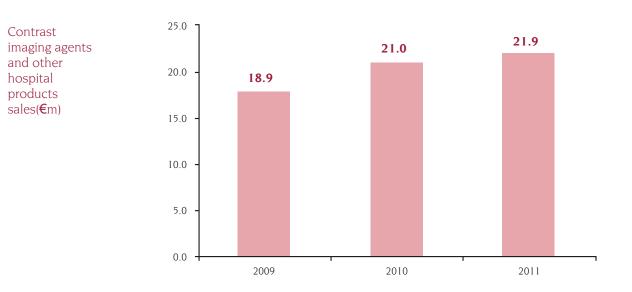
In the third quarter of 2011, no sales from **Levrison**<sup>®</sup> vaccine were registered, foreseeing the signature of the agreement between Alentia Biotech, joint venture of ROVI and Grupo Ferrer, and Novartis Vaccines & Diagnostics. Through this agreement, Alentia Biotech will be entitled to market seasonal flu vaccines under a co-marketing regime with Novartis Vaccines & Diagnostics for an estimated fiveyear period. Sales of Levrison<sup>®</sup> amounted to 4.3 million euros in 2010.

Sales of **Pneumovax**<sup>®</sup>-23, a non recurrent vaccine that helps to protect against serious infections caused by the bacterium pneumococcus, licensed by Sanofi Pasteur MSD in July 2008 for marketing by ROVI, reached 1.2 million euros in 2011. In 2010, no sales of Pneumovax-23 were registered.

In the second half of 2011, ROVI did not register sales from the **EMLA**<sup>®</sup> distribution, a topical anaesthetic licensed by AstraZeneca that has been marketed by ROVI since 1998. In June 2011, the EMLA<sup>®</sup> distribution agreement with AstraZeneca was replaced by a promotion agreement. Revenues related to EMLA<sup>®</sup> promotion amounted to 0.6 million euros in the second half of 2011. Revenues related to EMLA<sup>®</sup> distribution amounted to 2.6 million euros in the second half of 2010. Sales of **over-the-counter pharmaceutical products** declined by 5% to 6.9 million euros in 2011 compared to the previous year. This was mainly as consequence of ROVI divestiture strategy in this area.

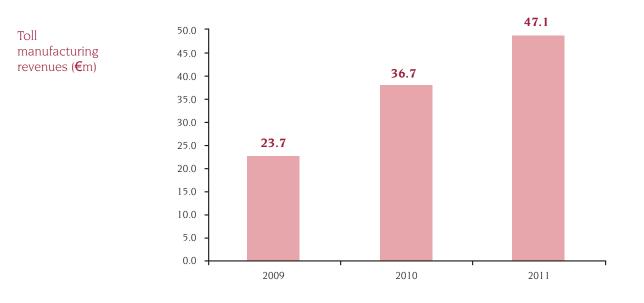


Sales of **contrast imaging agents** and other hospital products increased by 5% in 2011 to 21.9 million euros.



**Toll manufacturing** sales increased by 28% in 2011, to 47.1 million euros, compared with the previous year, mainly as a result of the implementation of the MSD manufacturing and packaging agreement, which was effective on 31 March 2010. Revenues from the MSD manufacturing and packaging agreement amounted to 32.2 million euros in 2011. The Frosst Ibérica plant has current manufacturing capabilities of 3 billion of capsules and 100 million of boxes. ROVI counts on a spare capacity of 40% in this plant which will allow it to acquire new customers in order to

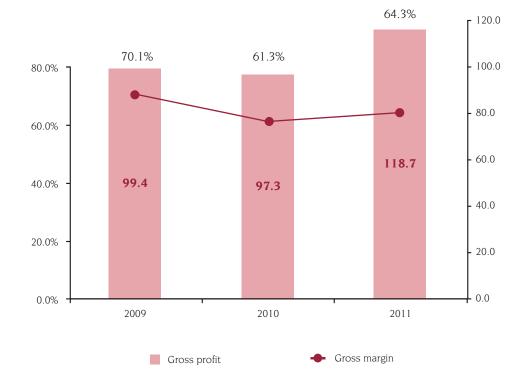
maximise the potential of the acquired infrastructure. In January 2011, ROVI signed an agreement with Farmalíder, a pharmaceutical company specialised in the development of branded, OTC, value-added, and traditional generic products, for the manufacturing, research and conditioning of pharmaceutical specialties based on Ibuprofen and Paracetamol. Farmalíder has undertaken to work towards providing ROVI with annual manufacturing that will represent an increase in the production of the plant of Frosst Ibérica by 10% to 15%.



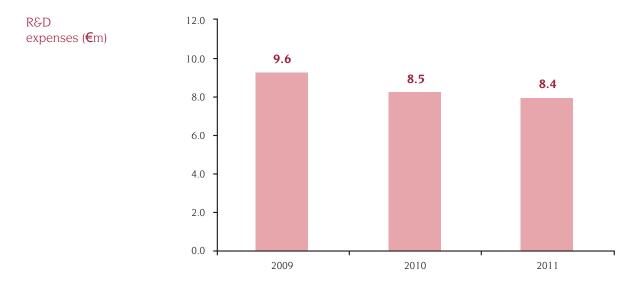
**Gross profit** increased by 22% in 2011 to 118.7 million euros, reflecting an increase in the gross margin to 64.3% in 2011 from 61.3% in 2010.

- Excluding the impact of the Fitoladius sale, gross margin increased to 63.2% in 2011 from 61.3% in 2010.
- Excluding the impact of other income (subsidies), which increased by 2.3 times in 2011, gross margin increased to 61.2% in 2011 from 60.4% in 2010 mainly due to the contribution of the Frosst Iberica plant for twelve months in 2011 compared to its contribution for nine months in 2010.

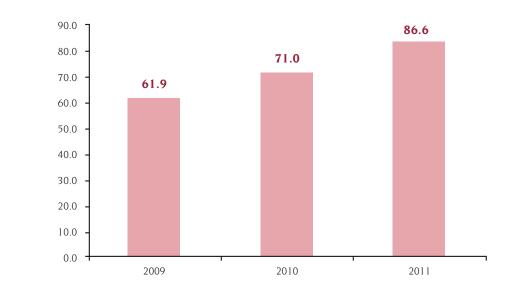
In 2011, ROVI continued to buy Bemiparin raw material at around 40 euros per million of international units and it expects that this stable trend continues during 2012.



Gross profit (€m) and gross margin (%) **Research and development expenses** decreased by 1% to 8.4 million euros, reflecting ROVI investments in products that are under development.

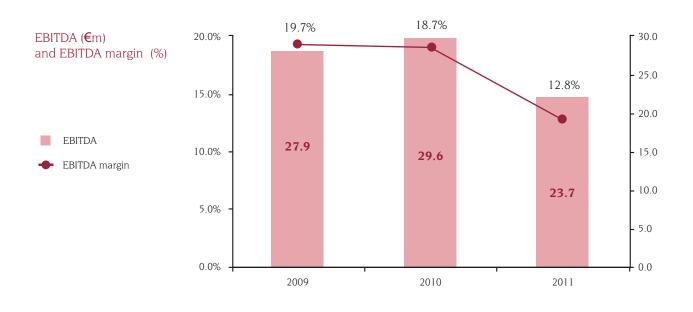


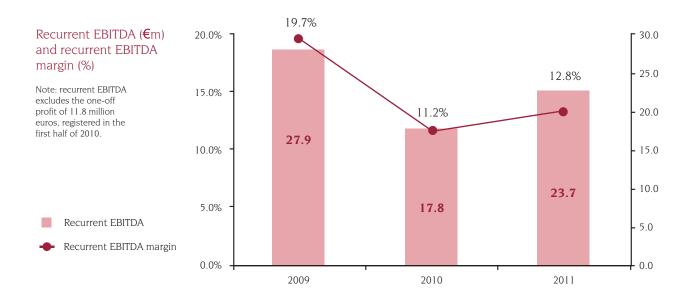
**Selling, general and administrative expenses** increased by 22% to 86.6 million euros in 2011 compared to the previous year, as a result of the MSD manufacturing and packaging agreement implementation, which was effective on 31 March 2010, and the launch of Vytorin and Absorcol, the first of the five licenses of MSD. Excluding the impact of the MSD toll manufacturing agreement in the first quarter of 2011, selling, general and administrative expenses increased by 16%. This 16% increase reflected ROVI investment effort in human capital to address primary care, main target of Vytorin<sup>®</sup> and Absorcol<sup>®</sup> products.



Selling, general and administrative expenses (€m) **EBITDA** decreased by 20% to 23.7 million euros in 2011, compared to the previous year, as a result of the impact of a one-off profit of 11.8 million euros, registered in the second quarter of 2010, caused by the difference between the fair value and the purchase price of the Frosst Ibérica assets.

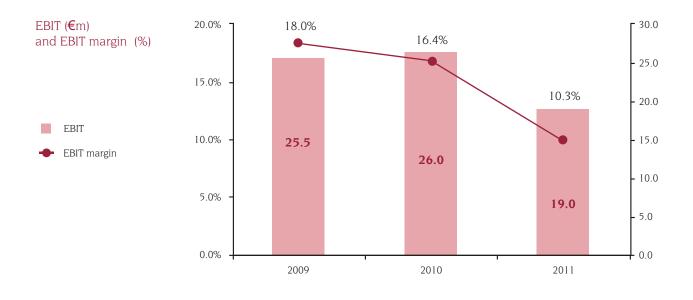
- Excluding the impact of this one-off profit, EBITDA increased by 33% in 2011.
- This 33% inrease includes a profit of 5.6 million euros related to Fitoladius product sale to a third part, registered in the second quarter of 2011.
- Excluding the impact of the Fitoladius sale, EBITDA increased by 2% in 2011, considering no Fitoladius sales registred from its sale to a third part in 2011. Considering that ROVI maintained the product in 2011, EBITDA increased by 8% in 2011.
- Excluding te impact of the Fitoladius sale and the impact of the measures to reduce the pharmaceutical expenditure, EBITDA inreased by around 22% in 2011.

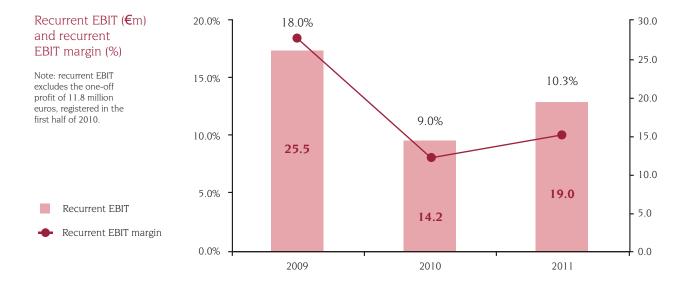




**Depreciation and amortisation expenses** increased by 31% in 2011, compared to the previous year, mainly as a result of the implementation of the MSD agreement and the new property plant and equipment and intangible assets purchases made during 2011.

**EBIT** decreased by 27% to 19.0 million euros in 2011, compared to the previous year, impacted by the same factors as EBITDA.





The **financial expense** line increased by 51% in 2011, compared to the 2010 financial year, mainly as a result of the implied interests increase related to the new reimbursable loans collected from 1 January 2011 to 31 December 2011 and of the implied interests increase related to the debt from purchase of Frosst Ibérica shares, registered as of 1 April 2010.

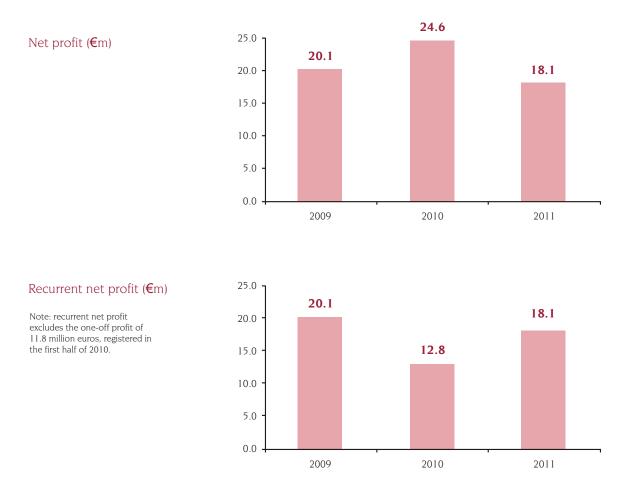
**Financial income** increased by 56% in 2011, compared to the previous year, as a result of higher returns on financial investments.

The **effective tax rate** was 4.2% in 2011 compared with 5.2% in 2010 despite the new tax measures package, approved by law on August 19, 2011 (http://www.boe.es/boe/dias/2011/08/20/pdfs/BOE-A-2011-14021.pdf), which affects tax bases. Previously, ROVI did not pay taxes on Frosst Ibérica profits as this company has negative tax bases and profits could be offset without limit. According to the new law, ROVI has to pay taxes on Frosst Ibérica profits as this company offset its profits by 50% of

the tax bases of the group during the period 2011-2013. Frosst Ibérica negative tax bases amounted to 56.3 million euros as of 31 December 2009 and increased significantly by the negative tax bases generated in 2010, which amounted to 20.2 million euros. In 2011, 6.4 million euros of these 76.5 million euros of negative tax bases were used.

The **net profit** of ROVI decreased by 26% to 18.1 million euros in 2011 compared to the previous year, impacted by the same factors as EBITDA. Recurrent net profit, which excludes the impact of the one-off profit of 11.8 million euros, rose 42% in 2011, above the single digit growth guidance provided for 2011

• Excluding the impact of the Fitoladius sale, recurrent net profit remained stable in 2011, considering o Fitoladius sales registered from its sale to a third part in 2011. Considering that ROVI maintained the product in 2011, recurrent net profit increased by 8% in 2011.



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As of 31 December 2011, ROVI had total debt of 50.7 million euros. Debt with public administration represented, as of 31 December 2011, 67% of total debt and 91% of total debt is 0% interest rate debt.

In thousand euros	31 / 12 / 2011	31 / 12 / 2010	<b>9</b> %
Loans from banks	4,695	6,891	( =0/
Debt with public administration	34,000	28,441	67%
Liabilities from financial leases	~	676	
Debt from purchase of shares	11,985	15,896	0%
Total	50,680	51,904	24%

Debt breakdown as of 31/12/2011 (%)

As of 31 December 2011, ROVI had a **gross cash** position of 61.7 million euros, compared to 59.8 million euros as of 31 December 2010, and a **net cash position** (financial assets and cash minus short term and long term debt) of 11.0 million euros, compared to 7.9 million euros as of 31 December 2010, providing it with a high level of financial flexibility.

**Free cash flow** amounted to 21.0 million euros in 2011 mainly due to the contracting of 25 million euros of short term bank deposits in 2010 which were sold in 2011.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that, "we are satisfied with the results for the full year 2011. Operating revenues increased by 16% from the previous year. This was in line with expectations despite the difficulties in the economic and regulatory environments. We attribute this out-performance to the strength of our leading products, which continue to gain share in their various market segments, and to the contribution of the MSD manufacturing and packaging agreement. Margins increased in 2011 mainly as a result of the contribution of the Frosst Iberica plant. We expect margins to be stable in 2012. It is very gratifying to witness the growth in the strength of our balance sheet and our excellent capacity to generate cash, which allow us to finance organic growth through the launch of new products, such as Vytorin and Absorcol, and to be in a strong position to benefit in the current operating environment as we will pay attention to potential opportunities to expand our sales base and better the utilisation of our asset base".

#### Guidance for 2012

Despite the impact of the new additional measures, approved in August 2011, for the rationalization of the pharmaceutical expenditure and the subsequent significant decrease expected for the Spanish pharmaceutical market also in 2012, ROVI expects to grow operating revenues from high single digit to low double digit for the full year 2012. ROVI expects its growth drivers to be Bemiparin, its existing portfolio of specialty pharmaceuticals, last launches such as Vytorin, Absorcol, Thymanax and Bertanel, new product distribution licenses and new customers in the toll manufacturing area.

#### **Dividend payment**

The ROVI General Shareholders Meeting, on 14 June 2011, approved the payment of a gross dividend of 0.17208 euros per share on 2010 earnings. This dividend was paid on 6 July 2011 and meant an increase of 22% compared to the dividend on 2009 earnings. In addition, this dividend implied the pay-out of 35% of consolidated net profit for 2010.

ROVI will pay a dividend of 0.1269 euros per share on 2011 earnings if the Shareholders General Meeting approves the application of the 2011 profit, under proposal of ROVI Board of Directors. This proposed dividend would imply the pay-out of 35% of consolidated net profit for 2011.

# Company information

# Corporate profile

ROVI is a fully integrated Spanish specialty pharmaceutical company engaged in the research, development, inlicensing, manufacturing and marketing of small molecule and specialty biologic drugs. The Company has a diversified portfolio of products that it markets in Spain through its specialized sales force, calling on specialist physicians, hospitals and pharmacies. ROVI's portfolio of 30 principal marketed products is currently anchored by the internallydeveloped, second generation low molecular weight heparin, Bemiparin. ROVI's research and development pipeline is focused primarily on the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products and other glycosaminoglycans and on the development of new controlled release mechanisms based on ISMTM technology, with the aim of obtaining new pharmaceutical products that enable the regular administration of formulations which are administered daily in chronic and prolonged treatments. ROVI manufactures the active biological ingredient (Bemiparin) for its principal proprietary products and for injectable pharmaceutical products developed by its in-house research team, and utilizes its state-of-the-art filling and packaging capabilities to provide a broad array of toll manufacturing services to leading international pharmaceutical companies, primarily in the area of pre-filled syringes. In addition, ROVI provides contract manufacturing and packaging services of solid oral pharmaceutical dosage forms, using the most enhanced technology, Roller Compaction. Additional information about ROVI is available on the company's website: www.rovi.es.





# The history of ROVI

## (1940s - 1970s

- Founded in December 1946.
- Marketing in Spain of licensed specialised products of international pharmaceutical companies.
- Marketing of sodium heparin in the 1950s and 1960s.
- Marketing of calcium heparin in the 1960s and 1970s.

## 1980s

1981: start of research into low molecular weight heparins.

Marketing of Bracco Imaging S.p.A. products in Spain.

## (1990s

- 1994: sale to Pfizer of ROVI glycerine suppositories.
- 1994: award of certificate for Good Practises in Manufacturing for manufacturing and packaging installations.
- 1995: start of supply of high added value packaging services to leading international pharmaceutical companies.

Development of a second generation of low molecular weight heparins, Bemiparin, called Hibor.

1998: introduction of Bemiparin in the Spanish market. Start of activities in Portugal.

## 2000 - 2011

- 2000: start of research into oral administration of Bemiparin.
- 2001: start of research into technology for enhancers for oral absorption of carbohydrates and protein ("EFOCAP").
- 2002: internationalisation of ROVI following overseas approval of Bemiparin.
- 2003: approval of Bemiparin in the UK, Ireland, Portugal, Austria, Greece and Italy.
- 2003: increased international coverage, whether in stages of registration, pre-registration, or marketing, in a total of 59 countries.
- 2003: Prince Felipe prize for Business Excellence in technological Innovation.
- 2004: start of research into technology for release of oral carbohyrdrates and proteins ("OCAP").
- 2004: sale of the generics division.
- 2005: licensing agreement with Laboratoires Servier for marketing of Osseor.
- 2006: start of construction of R&D centre for Bemiparin in Granada.
- 2007: marketing agreement with Laboratoires Servier for Corlentor.
- 2007: acquisition of Bertex, a German company specialising in technology for release injectable micro-particles.
- 2008: agreement with Sanofi Pasteur MSD for marketing of Pneumovax-23.
- 2008: agreement with Merck Sharp & Dhome International for marketing of EXXIV.
- 2009: strategic pharmaceutical manufacturing and marketing agreement with Merck Sharp & Dohme (MSD) in Spain.
- 2009: signing of a protocol of intentions with the Spanish government for the development of a centre for the research and production of vaccines for seasonal and pandemic flu in Spain.
- 2010: agreement with EBEWE for the marketing of Bertanel and with Laboratoires Servier for the marketing of Thymanax.
- 2011: launch of Absorcol and Vytorin, the first of the five licenses from MSD.
- 2011: agreement of Alentia Biotech, a joint venture of Ferrer and ROVI, with Novartis Vaccines for the transfer of the technology for the production of flu vaccines.

## Management team

#### Mr. Juan López-Belmonte López

He holds a degree in business and economics from the Universidad Complutense de Madrid. He has served as the Chairman of our Board of Directors for over 18 years. He is a member of the Board of Directors of Farmaindustria,



the Madrid Chamber of Commerce, the Andalusia Technology Corporation Association, the Board of Directors and Executive Committee of Madrid Business Confederation and a member of the Management Board of ANEFP and of the Board of Directors of CEIM.

#### Mr. Juan López-Belmonte Encina

He holds a degree in business and economics from CEU San Pablo de Madrid, with an emphasis in auditing. He is a shareholder of Inversiones Clidia, S.L. (and controlling shareholder of the Company) and our Chief Executive Officer.



He began his career carrying out diverse roles for various international pharmaceutical companies including the Nielzen Group in Spain, the Tyco Group in the United States and Boots Pharmaceutical in the United Kingdom. He has been with our Company since 1994 and served as General Director from October 2001 and as Chief Executive Officer from October 2007.

#### Mr. Iván López-Belmonte Encina

He holds a degree in business and economics from the Universidad Complutense de Madrid, with an emphasis in auditing. He is a shareholder of Inversiones Clidia, S.L. (and controlling shareholder of the Company) and our



Corporate Development Director. He is also a member of our Board of Directors. He began his career in Germany working for such companies as Amerscham, which focuses on nuclear medicine, and Hexal AG, a pharmaceutical company specializing in generics. He joined our Company in 1994 and served as Co-General Director from 2001 and as Director of Corporate Development from September 2007.

#### Mr. Javier López-Belmonte Encina

He holds a degree in business and economics from the Colegio Universitario de Estudios Financieros (CUNEF) de Madrid, with an emphasis in finance. He is our Chief Financial Officer and a member of our Board of Directors. He began



his career in the banking industry in 1998 as an analyst of the former Argentaria, S.A. in the United Kingdom and also worked for Medeva Pharma in the United Kingdom. He joined our Company in 2000 and served as Chief Executive Officer from 2001.

#### Mr. Javier Martínez González

A graduate in Medicine and Surgery and a Specialist in Pharmaceutical Medicine from the Faculty of Medicine of the Universidad Complutense of Madrid. He was Doctor in Primary Care and the Special Emergency Service of INSALUD until



1990. He then pursued his professional career in clinical research in the Scientific Department of ALK-Abelló in Madrid and in 1993 joined Laboratorios Pfizer, S.A. as Chief Doctor of the Therapeutic Area. He joined ROVI in 2002 as Medical Director, and is currently Director of Clinical Development.

#### Mr. Juan López Oriza

A graduate in Chemical Sciences, specialising in Industrial Chemistry, from the Universidad Complutense of Madrid. He has a degree in Marketing and Sales, with several courses and seminaries in INSEAD, IE and IESE. Mr. López Oriza



has a long track record in the pharmaceutical sector, working in companies including UPSA Médica (currently part of the BMS group), Duphar Farmaceútica (previously part of Solvay Pharma group, recently acquired by Abbott) and in Pfizer España S.A. where he worked for 14 years, until 2006, as Head of Marketing of the Cardiovascular Area and International Speaker. From July 2006 until now he has been the Marketing and Training Director of ROVI.

#### Mr. Javier Angulo García

A graduate in Law from the University of Deusto, specialising in Financial Law. Until June 2000, he worked in the US multinational Guardian Llodio, as Labour Relations Officer, and from July 2000 until joining ROVI in 2007 he worked in



the German multinational pharmaceutical company Schering in Madrid, in the manufacturing and marketing of pharmaceutical products and nuclear medicine equipment, as Director of Administration and Labour Relations. He is currently the Human Resources Director of ROVI.

#### Mr. José Zapata Prieto

A graduate in Pharmacy from the Universidad Complutense of Madrid (1985-1990). He started his career in the pharmaceutical sector at L'Oréal Cosméticos (1991-1993). He joined ROVI in 1993, where he has worked as



Director of Quality, and he has been Industrial Director since April 2008. He holds a Master in the Pharmaceutical and Para-Pharmaceutical Industry from CESIF, a Master in Pharmaceutical Industry Management from IE ("Instituto de Empresa") and completed a Management Development Program at the University of Navarra.

#### Mr. Fernando Martínez Morales

A graduate in Industrial Technical Engineering from the Universidad Politécnica of Madrid. He has a long track record in the pharmaceutical sector, working at companies which include Laboratorios Andreu (currently Roche), Upjohn



Farmoquimica, Juste SAQF, Astrazeneca, where he worked until 2005 as Head of Sales for the four lines of specialists (Oncology, Hospitals, Urology and Psychiatry), and was subsequently Director of Sales at Astellas Pharma. He joined ROVI in March 2007 as Manager of Sales and has been Director of Sales since September 2009.

#### Mr. Pedro Carretero Trillo

A graduate in Biological Sciences of the Universidad Complutense of Madrid. He holds a Master's in Commercial Management and Marketing from ESIC, ESEM. He was previously employed as a Molecular Biology sales professional at



Cultek and as national head of sales and marketing for Diabetes at Emminens. He joined ROVI in 2002 as Head of Product for Hibor (Bemiparin) and is currently Director of Hospitals and Institutional Relations for Spain and Portugal.

#### Mr. Pablo Domínguez Jorge

A graduated in Economics and Business of the Universidad Autónoma of Madrid in 1991 with a Master's in Financial Markets from the Carlos V International Centre in 1992. He started his career at Pfizer España S.A. in 1992 and worked



there for 15 years, as Head of Treasury and Client Services. In 2007 he joined AstraZéneca España as National Manager of Hospital Accounts. In July 2007 he moved to ROVI, where he is Administrative Financial Director.

# Corporate social responsibility



is composed of the **ethical**, **social and environmental commitments** that ROVI has voluntarily assumed, as an active part of society, in order to contribute to social and economic progress and to improving people's quality of life.

#### SHAREHOLDERS

To create more value for the long term

#### SOCIETY

To contribute, in an active way, to the sustainable development of the Society

#### **ENVIRONMENT**

To protect the enviroment

## To offer a service based on quality and excelence SUPPLIERS To find in ROVI a partner for the mutual benefit

#### EMPLOYEES

**CUSTOMERS** 

To generate enthousiasm and to promote training and motivation

# With society

#### **Social activities**

In 2011, ROVI collaborated in various solidarity events by donating more than 1.50% of the profits of the group.

# With the environment

At ROVI we are convinced that the Protection of the Environment in which our business is carried out is the only way of carrying out sustainable activities that will be long lasting in time, that are integrated in society, and that are financially profitable.

#### **ISO 14001 Certification**

In 2011, our centres with the environmental certification ISO 14001:2004 were successfully submitted to annual follow-up and recertification audits. In addition, in 2011 the staff in our Granada plant worked hard in order to certify their systems in ISO 14011:2004 (January 2012).

#### **Raising environmental awareness**

- Environmental investments: in a continuous and sustained way, ROVI contributed with more than 188,000 euros to environmental investments, demonstrating that we are meeting our commitment to protect the environment.
- During 2011, ROVI continued to cooperate with the "Fundación + Árboles", an organisation which aims to encourage a new understanding of trees and to change our relationship with our environment. For this reason, in addition to the planting of 50 trees in the Sierra of Alcaraz, ROVI organized, during the Christmas period, the campaign "give a tree" among employees.



# With people

People are the main capital of ROVI. In a company with a long tradition in human resources, corporate values and culture are present every day in every employee.

#### SA-8000 Certification

The aim of the SA-8000 system is to provide a standard, based on the instruments of international human rights and on national labour laws, which protects and empowers all the personnel who come under the control and influence of a company: employees of the company itself, suppliers/subcontractors, and sub-suppliers. In 2011, the certification body changed and in January 2012 we successfully passed the certification audit. In accordance with this commitment to our employees, we have made the following improvements:

• Equal opportunities for all: the commitment of ROVI to its employees, who are the key to the success of the company, is based on helping them advance in their professional careers, balancing their personal and professional lives, and emphasizing employment stability.

ROVI is committed to the integration of people with disabilities. On 31 December 2011, almost 2% of the workforce was composed of disabled workers.

• Training of staff: more than 30,000 hours of training were provided in 2011.

		2007	2008	2009	2010	2011
	Number of employees	502	547	550	783	834
_	% Man	47.8%	44.8%	44.5%	54.3%	48.8%
and the second	% Woman	52.2%	52.2%	55.5%	45.7%	51.2%



# With clients

According to the quality line established, the satisfaction level of our customers was maintained above 75% in 2011.

# With suppliers

Because for ROVI suppliers are an essential element of the value chain, as they work with us and share in our overall responsibility, and they are a key part of the continuous improvement of our activity, we want the commitments of ROVI to be complied with by them as well.

Because of this, as well as the information we send with the commitments we have made, we have also established various procedures for selecting suppliers, including, in addition, to quality, other criteria related to the protection of the environment and social development.

Reflecting this, ROVI has used the services of various Special Employment Centres. These centres are companies whose main aim is to provide productive work, with a regular participation in the market, and a remunerated position, as well as services for personal and social adjustment, for disabled workers.

# With shareholders

ROVI's main commitment to its shareholders is to create higher value that is sustainable over time.

2011 operating revenues guidance, upgraded from low double digit to mid teens on November 8, 2011, was achieved. The company's credibility is based on its continued compliance with what it announces to its shareholders, potential investors and the financial community.



# Corporate governance

# Share Capital

As of 31 December 2011, the share capital of Laboratorios Farmacéuticos ROVI, S.A. fully subscribed and paid in and composed of ordinary shares each of nominal value of 0.06 euros, and represented by book entries, was as follows:



3,000,000.00

Number of shares

50,000,000

Number of voting rights

50,000,000

# Holders of Significant Shareholdings

The shareholders of significant stakes in the share capital of Laboratorios Farmacéuticos ROVI, S.A., either directly or indirectly, of above 3% of share capital, of which the Company is aware, according to the information contained in the official registers of the Comisión Nacional del Mercado de Valores on 31 December 2011, are as follows:

	% Direct	% Indirect	TOTAL
Inversiones Clidia, S.L.	63.594*	ŗ	63.594
Mr. Juan López-Belmonte López	3.232	63.594*	66.826
Banco Mare Nostrum, S.A.	4.441	-	4.441
Bestinver Gestion, S.A. SGIIC	~	3.117	3.117

(\*) Inversiones Clidia, S.L., which owns 63.594 percent of the share capital of the Company, is 50.002 percent owned by Mr. Juan López-Belmonte López.

# Board of Directors

#### Composition

In accordance with the Company Statutes, the Board of Directors of Laboratorios Farmacéuticos ROVI, S.A, must be composed by no less than five and nor more than fifteen members. In accordance with these provisions, the Board of Directors as of 31 December 2011 was composed as follows:

		mittee		Directors condition		ition
	Member of Board of Directors since	Appointments and Remuneration Committee	Audit Committee	Executive	External proprietary	Independent
Mr. Juan López-Belmonte López President and Chief Executive Officer	27/07/2007			$\bigcirc$		
Mr. Juan López-Belmonte Encina Chief Executive Officer	27/07/2007	$\bigcirc$		$\bigcirc$		
Mr. Enrique Castellón Leal Vicepresident	24/10/2007	$\bigcirc$	$\bigcirc$			$\bigcirc$
Mr. Javier López-Belmonte Encina Director	27/07/2007		$\bigcirc$	$\bigcirc$		
Mr. Iván López-Belmonte Encina Director	27/07/2007			$\bigcirc$		
Mr. Miguel Corsini Freese Director	17/06/2009	$\bigcirc$	$\bigcirc$			$\bigcirc$
Mr. Fco. de Paula Lombardo Enríquez Director	14/06/2011				$\bigcirc$	
Mr. Jose Félix Gálvez Merino Secretary non director						

On 22 February 2011, the CajaGranada Director announced his resignation. On the same day, Mr. Francisco de Paula Lombardo Enríquez was appointed by cooptation, at the proposal of CajaGranada, as external proprietary Director to fill the vacancy. This appointment was confirmed by the General Shareholders Meeting on 14 June 2011.

# Committees of the Board of Directors

#### **Appointments and Remuneration Committee**

The Appointments and Remuneration Committee is composed of three directors, the majority of whom are independent. Its main role is to inform and to present to the Board of Directors proposals on appointments and resignations of directors and top managers; to evaluate the competences, know-how and experience necessary on the Board, and the time and dedication that is required of each member to carry out a director's functions adequately; to establish and review the criteria that the composition of the management team of the Company must follow; and to monitor and ensure the transparency of the remuneration policy established by management. The Committee makes reports, establishes policies, and makes proposals on the areas of its competence, which are submitted to the Board of Directors for their consideration and, if applicable, approval.

#### **Audit Committee**

The Audit Committee is composed of three members of the Board of Directors, the majority of whom are independent, who are appointed based on their know-how and experience in the accounting, auditing, or risk management areas. The Committee meets each quarter in order to review the financial information that as a listed company the Company is required to publish regularly. The Committee, among other functions, monitors the process of preparing the financial information of the Company and the Group and confirms the accuracy of the information, regularly reviews the information and internal control systems and risk management policies, and monitors the independence and effectiveness of internal and external auditors. The Board of Directors must consider and come to decisions on any proposals and reports that are submitted to it by the Committee.



# Professional profile of members of the Board of Directors

#### **Mr. Juan López-Belmonte López** See section "Management Team" (page 62).

#### Mr. Juan López-Belmonte Encina

See section "Management Team" (page 62).

#### Mr. Javier López-Belmonte Encina

See section "Management Team" (page 62).

#### Mr. Iván López-Belmonte Encina

See section "Management Team" (page 62).

#### Mr. Enrique Castellón Leal

A graduate in Medicine and Surgery and a Specialist in Internal Medicine at the Universidad Complutense of Madrid and in Business and Economics at the Universidad Autónoma of Madrid. He holds a Master's in Public Health and a



Master's in Health Policy and Management from Harvard University. He was practitioner in the Internal Medicine Service of the Hospital Clínico San Carlos de Madrid, a member of the Medical Inspectors of Social Security, Director General of the Galician Health Service, Deputy Director for Health and Social Services in the Community of Madrid, and Undersecretary in the Ministry of Health and Consumers. He also regularly advises various foundations which carry out research in health services, and provides consulting services for Castellón Abogados. He has worked as a consultant in health policies for the Interamerican Development Bank (part of the World Bank), and is a founding partner and Chairman of the Board of Directors of CrossRoadBiotech SCR.

#### Mr. Miguel Corsini Freese

A Law graduate and an expert in employment law. His career was for many years associated with Renfe, where he was Chairman of the Board from 1996 to 2004. He is currently Vice Chairman of the Business Federation of Madrid



(CEIM) and a member of the Management Board of the Spanish Confederation of Business Organisations (CEOE). In October 2007, Mr Corsini was appointed first Vice Chairman of the Chamber of Commerce of Madrid. In January 2010, he was appointed member of the Control Commission of Caja Madrid. He is a member of the Board of Directors of various companies, including Mutua Madrileña Automovilista, San José Tecnologías, and Testa Inmuebles in Renta (Grupo Sacyr-Vallehermoso).

#### Mr. Francisco de Paula Lombardo Enríquez

He is currently Chairman of Corporación Empresarial CajaGranada, a company of which he has been a member of the Board since 2003, Chairman of the Board of Impluvium, member of the



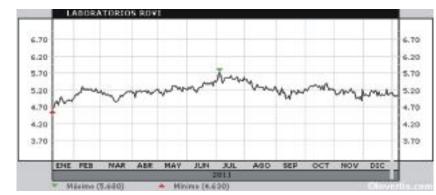
Board of Directors of Aquagest Sur (AGBAR group) since 2005 and chairman of the Audit Committee, member of the Board of Directors of LICO, which is owned by Spanish savings banks and Mapfre and which specialises in Leasing, Renting and Factoring, and since 2008 a member of the Board of Directors of OESÍA Network, a technology company with a presence in more than 12 countries. In this company, he is also a member of the Strategy Committee and the Appointments and Remuneration Committee, and Chairman of the Board of Atalaya Inversiones, which invests in listed companies (including ENCE, AXA and Uralita), 2007-2010 Vice Chairman of CajaGranada, 2005-2009 Chairman of the CSR and Social Work Committee of CajaGranada and member of the Strategy Committee, 2003-2007 Secretary of the Board of Directors and of the Executive Committee of Caja Granada, 2003-2005 Chairman of the Remuneration Committee of CajaGranada, 2003-2007 Director of Cervezas Alhambra and Grupo Alhambra Alimentaria, a holding company in the beer industry, of Mezquita y Alhambra, mineral water and food distribution, 2006-2008 Director of Navitas Energía, a renewable energy generation and distribution company. He has been a member of the Governing Council of the University of Granada and of the Social Council of the University of Granada.

# Financial report

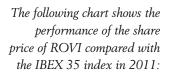
# Stock market capitalisation

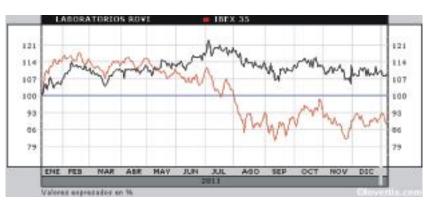
On the December 5th 2007, ROVI carried out an Initial Public Offering (IPO) of shares initially intended for qualified investors in Spain and to qualified or institutional investors abroad. The face value of the operation, without including the shares corresponding to the green shoe purchase option, was 17,389,350 shares already issued and in circulation with a nominal value of 0.06 euros per share, giving a total nominal amount of 1,043,361 euros. The offering price for the operation was 9.60 euros per share.

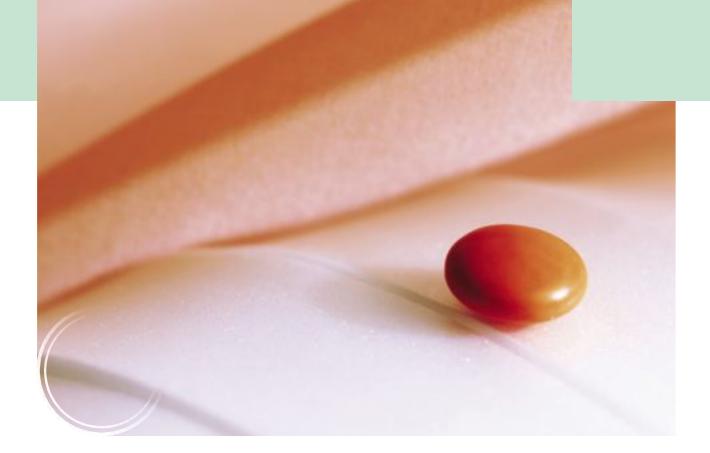
ROVI shares performed better than the IBEX 35 index in 2011. ROVI's share price increased by 5% from 3 January 2011 to 30 December 2011 compared with an IBEX 35 index fall of 13% in the same period.



The following graph shows the fluctuations of the share price in the stock market in 2011:







### Activity

Laboratorios Farmacéuticos Rovi, S.A. ("Rovi", "the Parent Company" or "the Company"), the parent company of the Group, was incorporated as a public limited company ("sociedad anónima") in Madrid on 21 December 1946. It is entered in the Companies Register of Madrid, sheet 1,179, folio 197 of volume 713 of Companies Book 283. The registered office of Laboratorios Farmacéuticos Rovi, S.A. is located at Julian Camarillo, 35, Madrid. Its head office is at the same address in Madrid.

The Company's principal activity is the sale of its own pharmaceutical products and the distribution of other products for which it holds licences granted by other laboratories for specific periods, in accordance with the terms and conditions contained in the agreements entered into with said laboratories.

ROVI is the parent of a pharmaceutical business group engaged in the production and sale of pharmaceutical products. The Group's main product is Bemiparin, a low molecular weight heparin, which is marketed in various countries.

The shares of the Company are listed on the Madrid, Barcelona, Bilbao and Valencia Stock Exchanges and included in the Spanish Stock Exchange Interconnection System (Continuous Market). The following financial information is extracted from the annual accounts of Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries as of and for the year ended 31 December 2011 audited by the auditing firm of PricewaterhouseCoopers Auditores, S.L. These annual accounts are presented in the Madrid commercial registry and copies may also be obtained from www.rovi.es.

#### Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries balance sheet (Thousand euros)

	2011	2010
	2011	2010
Assets		_
Non-current assets		
Property, plant and equipment	45,857	42,659
Intangible assets	2,736	2,290
Deferred tax assets	4,856	3,851
Available-for-sale financial assets	5,117	70
Financial receivables	325	2,086
	58,891	50,956
Current assets		
Inventories	41,306	41,824
Trade and other receivables	68,698	59,084
Current income tax assets	3,682	2,388
Bank deposits	6,000	25,000
Cash and cash equivalents	49,491	33,635
	169,177	161,931
Total assets	228,068	212,887
<b>F</b> 4		
Equity		_
Capital and reserves attributable		
to Company shareholders	2.000	2 000
Share capital	3,000	3,000
Legal reserve	600	600
Treasury shares	(1,922)	(1,960)
Retained earnings and voluntary reserves	93,920	77,914
Profit for the year	18,127	24,582
Reserve for available-for-sale assets	256	(2)
Total equity	113,981	104,134
Liabilities	-	
Non-current liabilities		
Financial debt	41,246	43,089
Deferred income tax liabilities	3,635	1,633
Non-current deferred revenues	12,450	12,404
	57,331	57,126
Current liabilities	,	,,
Trade and other payables	41,775	37,238
Financial debt	9,434	8,815
Current deferred revenues	4,298	4,334
Provision for other liabilities and charges	1,249	1,240
	56,756	51,627
	,	
Total liabilities	114,087	108,753
Total liabilities Total equity and liabilities	114,087	108,753

#### Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries income statement (Thousand euros)

	2011	2010
Revenue	184,706	158,645
Changes in inventories	(518)	11,434
Raw materials and consumables used	(68,921)	(74,255)
Employee benefit expenses	(51,133)	(42,207)
Other operating expenses	(43,893)	(37,306)
Depreciation, amortization and impairment charges	(4,709)	(3,586)
Recognition of government grants on non financial non-current assets and other	3,453	1,493
Other (losses)/gains - net	-	11,785
OPERATING PROFIT	18,985	26,003
Finance income	2,319	1,488
Finance costs	(2,376)	(1,570)
Finance costs - net	(57)	(82)
PROFIT BEFORE INCOME TAX	18,928	25,921
Income tax	(801)	(1,339)
PROFIT FOR THE YEAR	18,127	24,582
Earnings per share (basic and diluted) attributable to the shareholders of the Company (euros):		
Basic and diluted	0.36	0.49

Laboratorios Farmacéuticos Rovi, S.A.
and subsidiaries statement of changes in equity (Thousand euros)

	Share capital	Legal reserve	Treasury shares	Retained earnings and voluntary reserves	Profit for the year	Reserve for available- for-sale assets	TOTAL EQUITY
Balance at 1 January, 2010	3,000	009	(1,198)	64,741	20,141	(62)	87,205
Total comprehensive profit for the year	ı	ι	ı	l	24,582	77	24,659
Acquisition of treasury shares	ı	ι	(1,402)	ı	ı	ı	(1,402)
Re-issuance of treasury shares	ı	ι	640	43	ı	ι	683
Transfer of 2009 profit	ı	ι	l	20,141	(20,141)	l	l
Dividends 2009	l	l	l	(7,050)	l	l	(7,050)
Dividends treasury shares	l	l	l	39	l	l	39
Balance at 31 December, 2010	3,000	009	(1,960)	77,914	24,582	(2)	104,134
Total comprehensive profit for the year	l	l	l	l	18,127	258	18,385
Acquisition of treasury shares	l	l	(147)	l	l	l	(147)
Re-issuance of treasury shares	l	l	185	(29)	l	l	156
Transfer of 2010 profit	l	l	l	24,582	(24,582)	l	l
Dividends 2010	l	l	l	(8,604)	l	l	(8,604)
Dividends treasury shares	l	ı	l	57	l	l	57
Balance at 31 December, 2011	3,000	600	(1,922)	93,920	18,127	256	113,981

Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries cash flow statement (Thousand euros)

	2011	2010
	2011	2010
Cash flows from operating activities		
Profit before income tax	18,928	25,921
Adjustments for non-monetary transactions:		
Amortisation	4,709	3,586
Interest income	(2,319)	(1,488)
Gains or losses on sales of available-for-sale financial assets	(88)	18
Gains or losses on derecognition of financial assets and liabilities	109	(45)
Interest expense	2,376	1,552
Net changes in provisions	9	212
Income from acquisition of Frosst Ibérica, S.A.	-	(11,785)
Grant for non-financial fixed assets		
and distribution licence income	(2,435)	(1,380)
Changes in working capital		
Trade and other receivables	(12,598)	15,183
Inventories	518	(9,802)
Trade and other payables	4,139	1,885
Other collections and payments		
Proceeds from distribution licenses	700	~
Interest paid	(155)	(179)
Income tax cash flow	(1,209)	(2,488)
Net cash generated (used) from operating activities	12,684	21,190
Cash flows from investing activities		
Purchases of intangible assets	(800)	(1,143)
Purchases of property, plant and equipment	(7,553)	(4,433)
Purchases of available-for-sale financial assets	(6,400)	~
Proceeds from sale of available-for-sale financial assets	1,810	2,112
Liquidating current bank deposits (*)	25,000	~
Contracting current bank deposits (*)	(6,000)	(25,000)
Purchases of other financial assets	(65)	(182)
Increase in cash from acquisition of Frosst Ibérica, S.A.	~	3,034
Interest received	2,319	1,488
Net cash generated (used) in investing activities	8,311	(24,124)
Cash flows from financing activities		
C C	(8,613)	(5,902)
Repayments of financial debt		
Repayments of financial debt Proceeds from financial debt		
	12,012	14,262
Proceeds from financial debt Purchase of treasury shares		
Proceeds from financial debt Purchase of treasury shares Reissue of treasury shares	12,012 (147) 156	14,262 (1,402) 683
Proceeds from financial debt Purchase of treasury shares Reissue of treasury shares Dividends paid	12,012 (147) 156 (8,547)	14,262 (1,402)
Proceeds from financial debt Purchase of treasury shares Reissue of treasury shares Dividends paid Net cash generated in financing activities	12,012 (147) 156 (8,547) (5,139)	14,262 (1,402) 683 (7,011) <b>630</b>
Proceeds from financial debt Purchase of treasury shares Reissue of treasury shares Dividends paid	12,012 (147) 156 (8,547)	14,262 (1,402) 683 (7,011)

(\*) As of 31 December 2011, the Group held current bank deposits maturing at over three months of 6 million euros (25 million euros at 31 December, 2010). These current bank deposits are fully available.

# Property, plant and equipment

The breakdown of the movement on the different categories of property, plant and equipment is shown below:

	Land and buildings	Technical facilities, machinery & tools	Furniture fittings and other	IT equipment and vehicles	PPE in progress	Total
Balance at 01.01.10						
Cost or valuation	11,066	34,442	933	1,888	~	48,329
Accumulated depreciation	(2,622)	(11,901)	(438)	(829)	~	(15,790)
Net carrying amount 01.01.10	8,444	22,541	495	1,059		32,539
Additions	-	3,368	50	1,015	~	4,433
Change in consolidated group	8,070	207	570	55	238	9,140
Provision for depreciation	(785)	(2,003)	(97)	(568)	~	(3,453)
Balance at 31.12.10						
Cost or measurement	35,402	85,481	2,739	5,781	238	129,641
Accumulated depreciation	(19,673)	(61,368)	(1,721)	(4,220)	~	(86,982)
Net carrying amount 31.12.10	15,729	24,113	1.018	1,561	238	42,659
Additions	~	5,921	29	1,603	~	7,553
Retirements	(3,756)	~	-	1	~	(3,756)
Transfers	-	238	~	~	(238)	~
Eliminations from depreciation	3,756	-	-	~	~	3,756
Provision for depreciation	(792)	(2,612)	(103)	(848)	~	(4,355)
Balance at 31.12.11						
Cost or valuation	31,646	91,640	2,768	7,384	~	133,438
Accumulated depreciation	(16,709)	(63,980)	(1,824)	(5,068)		(87,581)
Net carrying amount 31.12.11	14,937	27,660	944	2,316	-	45,857

The amounts shown on the line "Change in consolidated group" relate to the property, plant and equipment recognized by the Group at fair value as a consequence of the acquisition of Frosst Ibérica, S.A.

In 2011 and 2010 there were no impairments of property, plant and equipment.

At 31 December, 2010, the land and constructions item included buildings under finance lease agreements with a net carrying amount of 626 thousand euros. These assets, which had been fully depreciated at the end of the 2011 reporting period, with an acquisition value of 3,756 thousand euros, were eliminated from the Group's property, plant and equipment on 31 December, 2011.

### Intangible assets

Movement on intangible assets was as follows:

	Patents and industrial property	Trademarks and licences	Computer software	Total
Balances at 01.01.10	_			_
Cost	573	96	375	1,044
Accumulated amortization	(5)	(27)	(38)	(70)
Net carrying amount 01.01.10	568	69	337	974
Additions 2010	~	~	1.143	1,143
Changes in consolidated group (net)	~	306	~	306
Amortization charge 2010	(5)	(24)	(104)	(133)
Balances at 31.12.10				
Cost	573	402	5,244	6,219
Accumulated amortization	(10)	(51)	(3,868)	(3,929)
Net carrying amount 31.12.10	563	351	1.376	2,290
Additions 2011	168	~	632	800
Amortization charge 2011	(26)	(16)	(312)	(354)
Balances al 31.12.11				
Cost	741	402	5,876	7,019
Accumulated amortization	(36)	(67)	(4,180)	(4,283)
Net carrying amount 31.12.11	705	335	1,696	2,736

Under the agreements signed between Rovi Imaging, S.L. and Merck Sharp & Dohme (MSD), an intangible asset of 306 thousand euros was integrated into the Group in 2010. This intangible asset relates to the acquisition of the registrations and trademarks of the products Prinivil, Ameride and Tryptizol, which, although it was signed at the same time and in the same context as the agreement signed with MSD, is considered a separate transaction from the acquisition of the business overall, since these assets are not necessary for Frosst's operations and did not previously belong to said company. For this reason, in accordance with International Accounting Standard 38 on Intangible Assets (IAS 38), they were recognized at acquisition cost and not at its acquisition-time fair value (1,521 thousand euros). Additionally, the acquisition of Frosst Ibérica, S.A. meant the integration of 3,726 thousand euros of computer software in 2010, which, at the time of acquisition, had been fully amortized.

In previous years, the Group acquired intangible assets for 580 thousand euros relating to patents and industrial property. The acquisition was made through the purchase of 100% of the shares of the German company Bertex Pharma GmbH. As part of the acquisition agreement, a payment of 100 thousand euros was made during the year 2011, meaning an increase of said amount in the value of these intangible assets.

Research and development expenditure incurred in 2011 was 8.414 thousand euros (8,487 thousand euros in 2010).

### Inventories

The inventories purchase/sale commitments for the Group at the year end were as normal in its course of its business. Management estimates that meeting these commitments will not generate losses for the Group. The Group has insurance policies to cover the risks the inventories are exposed to. The insurance cover is considered sufficient.

	2011	2010
Raw materials & other consumables	10,481	15,628
Work in progress & semi-finished goods	11,419	6,255
Finished goods produced internally	6,649	3,764
Marketing products	12,757	16,177
Total inventories	41,306	41,824

# Trade and other receivables

The breakdown of current trade and other receivables is as follows:

	2011	2010
Trade receivables	60,540	46,805
Less: provision for impairment of receivables	(1,172)	(945)
Trade receivables – net	59,368	45,860
Other receivables	659	1,487
Receivables from related parties	743	743
Deposits	1,077	1,077
Employee advances	163	333
Public authorities	7,013	11,670
Total trade and other receivables	69,023	61,170
Less: Non-current portion: Financial receivables	325	2,086
Current portion	68,698	59,084

## Application of profit

The proposed application of the profit for the year 2011 and other reserves of the parent company, determined on the basis of generally-accepted accounting principles in Spain, that will be submitted to the General Meeting of Shareholders, together with the application approved for 2010 based on the profit of the parent company, is as follows:

	2011	2010
Basis of application		
Profit for the year	7,704	11,758
Application		
Dividend	6,345	8,604
Retained earnings	1,359	3,154
	7,704	11,758

## Trade and other payables

The breakdown of current trade and other payables is as follows:

	2011	2010
Trade payables	33,507	30,305
Payables to related parties	1,128	1,141
Outstanding remuneration	3,732	3,785
Public authorities	3,305	1,850
Other payables	103	157
Total trade and other payables	41,775	37,238

## Financial debt

	2011	2010
Non-current		
Bank borrowings	2,840	4,967
Debt with government entities	30,582	26,386
Debt on acquisition of Frosst Ibérica, S.A.	7,824	11,736
	41,246	43,089
Current		
Bank borrowings	1,959	1,924
Debt with government entities	3,315	2,055
Finance lease liabilities	-	676
Debt on acquisition of Frosst Ibérica, S.A.	4,160	4,160
	9,434	8,815
Total financial debt	50,680	51,904

At 31 December, 2011, ROVI had total debt of 50,680 thousand euros. Debt with public administration represented 67% of total debt in 2011, from 55% in 2010. This section mainly contains the reimbursable advances that, since the 2001 financial year, Laboratorios Farmacéuticos ROVI, S.A., along with other companies in the Group since 2007, has been awarded by official national and regional bodies to fund different R&D projects. These reimbursable advances, as they are subsidies, do not accrue any interest charges. As of 31 December, 2011, 91% of the Group total debt is 0% interest rate debt. Another significant heading among the borrowings is that for bank borrowings, which reflects loans with three financial institutions as of December 31, 2011. Parts of the financial expenses generated by these transactions have also been subsidized by official entities.

The Group's objective in relation to the management of capital is to maintain a low level of leveraging which will make it easier for the Group to obtain additional borrowings if required in order to make new investments. The leverage indexes or gearing ratios at 31 December 2011 and 2010 were as follows:

	2011	2010
Financial debt	50,680	51,904
Less: Cash and cash equivalents	(49,491)	(33,635)
Net debt	1,189	18,269
Equity	113,981	104,134
Leverage index/gearing ratio	1.04%	17.54%

### Deferred revenues

	2011	2010
Non-current		
Deferred revenues on distribution licenses	1,234	970
Deferred revenues on grants	11,216	11,434
	12,450	12,404
Current		
Deferred revenues on distribution licenses	129	149
Deferred revenues on grants	4,169	4,185
	4,298	4,334
Total deferred revenues	16,748	16,738

The caption "Deferred revenues on distribution licenses" records amounts collected from the rights to market Hibor in a number of countries. The Group defers the revenue over the terms of the contracts, which have a duration of between 10 and 15 years. In 2011 deferred revenues on distribution licences have been registered related to new distribution Hibor contracts in several Africans countries.

The "Deferred revenues on grants" caption shows the amounts pending recognition in the income statement for reimbursable and non-reimbursable grants received by the Group. These amounts are credited to the income statement over the useful life of the subsidized assets.

- a) The most significant non-reimbursable grants pending recognition in the income statement are related to the construction of the bemiparin plant in Granada, which came into operation in 2009:
  - Non-reimbursable grant granted by the Andalusian Innovation and Development Agency (Innovation, Science and Enterprise Department) for 5,431 thousand euros. This

grant was received in November 2008 and recognition in the income statement commenced in 2009, when the assets for which it was granted began to be depreciated. The amount recognized for this grant under the caption "Deferred revenues on current and non-current grants" at 31 December, 2011 was 4,694 thousand euros (4,989 thousand euros at 31 December, 2010).

Also for the construction of the Granada bemiparin plant, the Innovation, Science and Enterprise Department of the Andalusian Regional Government granted the Group a nonreimbursable grant of 2,200 thousand euros. Recognition of this grant in the income statement commenced on 1 January, 2010 and the amount recognized under the caption "Deferred revenues on current and non-current grants" at 31 December, 2011 was 1,923 thousand euros (2,061 thousand euros at 31 December, 2010). This grant had not yet been collected at 31 December, 2011.

- b) The most significant amounts recognized as deferred revenues related to reimbursable grants granted by government entities relate to construction of the vaccine plant in Granada:
  - In 2009, the Group received a decision whereby the Ministry of Health and Social Policy granted a repayable loan of 11,900 thousand euros for development of the vaccine against seasonal influenza and the construction of a new vaccine production plant in Granada. This loan was collected in 2010. A subsidized interest rate is associated to this loan and is recognized under the caption "Deferred revenues on current and non-current grants" for an amount of 3,587 thousand euros at 31 December, 2011 (3,587 thousand euros at 31 December, 2010).
- In relation to the construction of the influenza vaccine production plant in Granada, in 2010 the Group received a decision whereby the Ministry of Health, Social Policy and Equality granted it a repayable loan of 9,500 thousand euros for 2010 and 1,000 thousand euros for 2011. At 31 December, 2011, only the annual loan for 2010 had been collected. A subsidized interest rate valued at 3,552 thousand euros is associated to the 2010 loan. 47 thousand euros of this amount was allocated to the income statement in 2011. The 2011 annual loan bears a subsidized interest rate valued at 402 thousand euros, which, at 31 December, 2011, was recognized in full as deferred revenue from non-current grants, while the receivable was recognized under "Current trade and other receivables".

#### Analysis of the main items in the income statement for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

#### Revenues

	2011	2010
Sale of goods	129,783	117,266
Sale of services	47,120	36,719
Revenue from distribution licenses	406	59
Other revenues	7,397	4,601
Total revenues	184,706	158,645

### Sale of goods by product line

	2011	2010
Pharmaceutical products	100,512	87,701
Contrast agents and other hospital products	21,941	20,957
Non prescription pharmaceutical products	6,861	7,234
Cosmetic medicine products	469	1,374
Total sale of goods by product line	129,783	117,266

Sales of prescription-based pharmaceutical products rose 15% to 100.5 million euros in 2011. Excluding the impact of the measures to reduce the pharmaceutical expenditure, sales of prescription-based pharmaceutical products rose around 19% in 2011.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, maintained a growth rate, with sales up 15% to 50.5 million euros. Sales of Bemiparin in Spain (**Hibor**<sup>®</sup>) increased by 14% to 35.4 million euros, while international sales rose by 18% from last year supported by the increased presence of Bemiparin, through strategic alliances, in countries where it was already present, and by the launch of the product in four new countries, Bolivia, Byelorussia Russia and Bahrain, during 2011.

Sales of **Corlentor**<sup>®</sup>, a specialty product for stable angina and chronic heart failure<sup>1</sup> from Laboratoires Servier, rose 40% in 2011, to 7.1 million euros. In February 2012, Corlentor<sup>®</sup> has been approved by the European Commission for the treatment of patients with chronic heart failure<sup>1</sup>. The European Commission's decision to authorise this new indication for Corlentor<sup>®</sup> followed the review of data from the SHI<sub>r</sub>T trial, the largest-ever morbi-mortality study of treatments for chronic heart failure involving more than 6000 patients. It demonstrated that the treatment signifi-

#### Analysis of the main items in the income statement for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

cantly reduced the risk of death and hospitalisation from heart failure, and improved the quality of life of people living with the disease.<sup>23</sup> This reduction in mortality was highly significant in patients with a heart rate of 75 beats per minute (bpm), or above, for whom Corlentor<sup>®</sup> is now indicated.

Sales of **Osseor**<sup>®</sup>, a specialty product for the treatment of postmenopausal osteoporosis from Laboratoires Servier, increased by 7% in 2011, to 7.1 million euros.

Sales of **Exxiv**<sup>®</sup>, a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 3% to 8.0 million euros in 2011 mainly due to a slight deceleration of the COX-2 market.

Sales of **Thymanax**<sup>®</sup>, an innovative antidepressant from Laboratoires Servier, launched in March 2010 and for

which ROVI has a co-marketing agreement covering Spain, increased by 2.7 times to 8.6 million euros in 2011.

Sales of **Vytorin**<sup>®</sup> and **Absorcol**<sup>®</sup>, the first of the five licenses of MSD, launched in January 2011, reached 5.7 million euros in 2011.

Sales of **over-the-counter pharmaceutical products** declined by 5% to 6.9 million euros in 2011 compared to the previous year. This was mainly as consequence of ROVI divestiture strategy in this area.

Sales of **contrast imaging agents** and other hospital products increased by 5% in 2011 to 21.9 million euros.

(1) EMA announcement.

(2) Swedberg K, Komajda M, Böhm M et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study. Lancet 2010; 376:875-85.
 (3) Ekman I, Chassany O, Komajda M et al. Heart rate reduction with ivabradine and health related quality of life in patients with chronic heart failure: results from the SHIFT study. Eur Heart J. 2011; DOI: 10.1093/eurheartj/ehr343. Available at: http://eurheartj.oxfordjournals.org

## Employee benefit expenses

	2011	2010
Wages and salaries	42,857	35,473
Social security costs	8,225	6,683
Pension costs - defined-contribution pension plans	51	51
Total employee benefit expenses	51,133	42,207

#### Analysis of the main items in the income statement for Laboratorios Farmacéuticos Rovi, S.A. and subsidiaries (Thousand euros)

### Main financial Ratios

	2011	2010
Financial ratios (thousand euros)		
Gross profit <sup>(1)</sup>	118,720	97,317
% Gross profit / Revenues	64%	61%
EBITDA <sup>(2)</sup>	23,694	29,589
% EBITDA / Revenues	13%	19%
Profit for the year	18,127	24,582
Total equity / Total equity and liabilities	50%	49%
Borrowings (3)	50,680	51,904
Borrowings / Total equity and liabilities	22%	24%
Working capital <sup>(4)</sup>	112,421	110,304
Net cash <sup>(5)</sup>	11,005	7,850
% Net cash / Total equity and liabilities	5%	4%

(1) Operating revenues (revenues + recognition of government grants on non financial non current assets and others) +/- changes in inventories of finished goods and work in progress - raw materials and consumables used.

(2) Calculated as operating profit + depreciation, amortisation and impairment charges.

(3) This reflects the total of current and non-current borrowings.

(4) Calculated as total current assets - total current liabilities.

(5) Net cash includes available-for-sale financial assets, deposits (included within the heading of Trade and other receivables), cash and cash equivalents and derivative financial instruments (net), minus borrowings (bank borrowings, debts with Government entities, third party debts, finance lease liabilities and accrued interests).

This report contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this report represent ROVI's expectations and beliefs as of the date of this report. ROVI

### Forward-looking statements

anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this report.